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MYRIAD GENETICS, INC.

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FINANCIAL

ANNUAL REPORT 2004

**CORPORATE OFFICE**

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Salt Lake City, UT 84108  
Phone: 801.584.3600  
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**LEGAL COUNSEL**

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Boston, MA 02111

**TRANSFER AGENT**

**AND REGISTRAR**  
American Stock Transfer &  
Trust Company  
59 Maiden Lane  
New York, NY 10038

**INDEPENDENT AUDITORS**

KPMG LLP  
15 West South Temple  
Suite 1500  
Salt Lake City, UT 84101

**ANNUAL MEETING**

The Annual Meeting of Shareholders  
will be held at the offices of  
Myriad Genetics, Inc.,  
320 Wakara Way, Salt Lake City, Utah,  
on Thursday, November 11, 2004,  
at 9:00 a.m.

**[www.myriad.com](http://www.myriad.com)**

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October 2004

**To Our Shareholders,**

We are pleased to report that Myriad enjoyed another year of both business and scientific achievement. We have advanced our strategy of combining a strong focus on therapeutic product development with a profitable operating business in predictive medicine. These complimentary opportunities have enabled us to take full advantage of scientific breakthroughs, while managing risk to the Company and maintaining a modest rate of cash expenditure. This strategy has kept us on track toward realizing our objective of being a world-leading biopharmaceutical company specializing in the prediction, prevention and treatment of human disease.

The first phase in realizing this goal, building a significant and growing business in predictive medicine, has been successfully implemented. We believe that the field of predictive medicine will continue to revolutionize the practice of medicine by identifying an individual's risk of developing a serious disease later in life. This knowledge can be used to guide the individual's healthcare to reduce the risk of developing future disease and perhaps even prevent the disease altogether.

In fiscal 2004, we achieved record product revenues, record gross profit margins and increased market penetration across all of our predictive medicine product lines. These revenues totaled \$43 million in 2004 and have been growing at an average annual rate of approximately 25%. Gross profit margins on predictive medicine revenues have also increased steadily, reaching a record 68% in 2004. Building this business has taken patience and perseverance. It has required leadership and the conviction that we are pioneering new ideas that will bring great advances in medicine. Our reward for this effort has been in the tremendous satisfaction each of us feels every time someone tells us that one of our cancer predictive tests has saved his or her life. In each instance, we hear of the new power individuals feel to take control and change their lives for the better due to the knowledge they have gained from these tests. These occurrences motivate us to continue our efforts to make these potentially life-saving technologies available to men and women who are at risk of cancer throughout the world.

We have also been actively preparing to make the second phase of our objective a reality. We believe that the future of medicine lies in the creation of new classes of drugs that treat the cause, not just the symptoms, of disease. We further believe that by understanding the molecular basis of disease, a new generation of therapies can be designed to help prevent disease. Myriad has carefully and conscientiously constructed an efficient drug discovery and development system designed to bring new drug candidates through the development process with the goal of delivering life saving and life enhancing therapeutic products to the market. Our lead drug candidate, Flurizan, is undergoing a Phase 2 clinical study in patients with mild-to-moderate Alzheimer's disease. The study is designed to evaluate the ability of Flurizan to slow the decline in cognitive function caused by Alzheimer's disease. We anticipate the completion of this study in March of 2005, with the presentation or publication of the results to follow.

*(CONTINUES ON REVERSE SIDE)*

In the field of cancer therapy, Myriad intends to move away from drugs that are toxic to all of the cells of the body. Instead, we are working to strike at the ability of cancer cells to avoid the normal process of cell aging and death known as apoptosis. By driving these cancer cells back into the programmed cell death pathway, our drug candidates offer the potential to treat the cause of cancer without the significant toxic side effects that have been associated with traditional chemotherapies.

Our cancer drug development team intends to submit two IND applications to the FDA in calendar year 2004, before initiating clinical trials with new drug candidates. These candidates, designated MPC-6827 and MPI-176716, work at two different points in the apoptosis biochemical pathway. (Cells that by one means or another manage to avoid this normal control process become essentially immortal and grow out of control, at which point they are cancerous.) In preclinical studies, each drug candidate forces cancerous cells back into the apoptosis pathway where they are eliminated. MPI-176716 works at a later stage in the pathway and, in laboratory studies, is especially effective against ovarian cancer cells, and also shows synergy in improving the cancer killing ability of two marketed cancer drugs, carboplatin and taxotere, commonly used in treating ovarian cancer. MPC-6827 works at an earlier stage in the pathway, and in clinical studies has shown potency against a wide range of tumors including those from the breast, colon, prostate and pancreas.

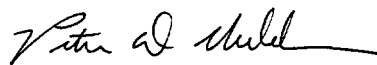
In order to treat complex diseases such as cancer effectively, it is essential to understand how the body uses genetic information, how the disruption of important biological pathways can lead to disease and how drugs can be developed to prevent, halt or reverse disease progression. Myriad scientists are continually advancing technologies toward more efficient discovery and validation of novel molecular drug targets.

We have exciting drug candidates to develop, the resources required to develop them, a growing high-margin predictive medicine business and compounds in the clinic that address large unmet patient needs. We are confident that we are in position to see our objectives become reality and we are committed to making 2005, and each successive year, Myriad's best year ever. We would like to thank all of our dedicated and hard working employees, without their expertise and great efforts, Myriad's progress would not be possible. Finally, we are grateful to you, our shareholders, for your commitment, confidence and support.

Sincerely yours,



**DALE STRINGFELLOW, PH.D.**  
Chairman of the Board



**PETER D. MELDRUM**  
President and CEO

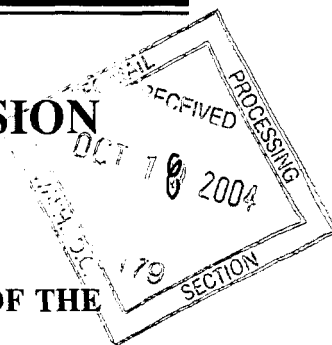
*This letter contains forward-looking statements, including statements about our strategy, growth and future operating results and the progress and development of our drug candidates. These statements are based on our current beliefs and expectations but are subject to risks and uncertainties that could cause actual results to differ materially from those set forth in or implied by these forward-looking statements. For more detailed information on the risks and uncertainties associated with these statements, see the section entitled, "Risk Factors" in our Annual Report on Form 10K for the fiscal year ended June 30, 2004 that accompanies this letter.*



MYRIAD.

MYRIAD GENETICS, INC., 320 WAKARA WAY, SALT LAKE CITY, UTAH 84108

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-K**



(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2004

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-26642

**MYRIAD GENETICS, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction  
of incorporation or organization)*

**87-0494517**  
*(I.R.S. Employer Identification No.)*

**320 Wakara Way, Salt Lake City, UT**  
*(Address of principal executive offices)*

**84108**  
*(Zip Code)*

Registrant's telephone number, including area code: **(801) 584-3600**

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Exchange Act:

Common Stock, \$.01 Par Value Per Share

Preferred Share Purchase Rights

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act) Yes ☒ No ☐

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the price at which the common stock was last sold on December 31, 2003, the last business day of the registrant's most recently completed second fiscal quarter, was \$336,988,687.

As of September 1, 2004 the registrant had 30,653,814 shares of common stock outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on November 11, 2004.

## PART I

### Item 1. BUSINESS

#### Overview

We are a leading biopharmaceutical company focused on the development and marketing of novel therapeutic and molecular diagnostic products. We employ a number of proprietary technologies that permit us to understand the genetic basis of human disease and the role that genes and their related proteins play in the onset and progression of disease. We use this information to guide the development of new healthcare products that treat major diseases and assess a person's risk of disease later in life.

We believe that the future of medicine lies in the creation of new classes of drugs that treat the underlying cause, not just the symptoms, of disease and that may be useful in disease prevention. By understanding the genetic basis of disease, we believe we will be able to develop drugs that are safer and more efficacious. In addition, we believe that advances in the emerging field of predictive medicine will improve our ability to determine which patients are subject to a greater risk of developing these diseases and who therefore would benefit from these new preventive therapies.

Myriad researchers have made important discoveries in the fields of cancer, Alzheimer's disease, and infectious diseases such as AIDS. These discoveries point to novel disease pathways that may pave the way for the development of new classes of drugs. Flurizan™, our lead therapeutic candidate for the treatment of Alzheimer's disease, recently completed a phase 1 human clinical trial which evaluated the safety of Flurizan™ in the elderly population. The study found that Flurizan™ appeared to be safe and well tolerated in the healthy older volunteers. We are currently conducting a phase 2 human clinical study in Europe and Canada to assess the efficacy of Flurizan™ for the treatment of patients with mild to moderate Alzheimer's disease. Flurizan™ is also in a large, multi-center phase 2/3 human clinical trial in the U.S. for the treatment of patients with pre-metastatic prostate cancer. We intend to independently develop and, subject to regulatory approval, market our therapeutic products, particularly in the area of cancer, viral disease, and Alzheimer's disease.

We also have a number of drug candidates in late-stage preclinical development in the areas of cancer, emesis, and AIDS. MPI-176716 was developed by our researchers based on the discovery of a novel drug target for the induction of programmed cell death, or apoptosis. This drug candidate causes tumor remission in animal models and appears to be synergistic with both the taxane and platin classes of chemotherapeutic drugs. MPC-6827 is also a broad apoptosis-inducing cancer drug candidate that has shown strong activity against cancers of the ovary, breast, prostate, pancreas and skin (melanoma). These cancer drug candidates are expected to enter human clinical testing next year.

As published in the scientific journal *Cell*, our scientists and their collaborators discovered the viral budding mechanism in HIV and other viruses. This discovery led to the development of MPI-49839, a viral budding inhibitor and new class of drugs for the treatment of AIDS. MPI-49839 has demonstrated strong anti-HIV activity and has been shown to be effective against many of the drug resistant strains of HIV. MPI-49839 is in late-stage preclinical formulation in preparation of human clinical testing in the near future.

We also have developed and commercialized a number of innovative predictive medicine products, including BRACAnalysis®, which assesses a woman's risk of developing breast and ovarian cancer, COLARIS® and COLARIS AP®, which determine a person's risk of developing colon cancer, and MELARIS®, which assesses a person's risk of developing malignant melanoma, a deadly form of skin cancer. In the United States we market these products using our own 100 person sales force. Predictive medicine revenues were \$43.3 million for the year ended June 30, 2004.



We have devoted substantially all of our resources to undertaking our drug discovery and development programs, operating our predictive medicine business, and continuing our research and development efforts. Our revenues have consisted primarily of sales of predictive medicine products and research payments. We have yet to attain profitability and, for year ended June 30, 2004, we had a net loss of \$40.6 million. As of June 30, 2004 we had an accumulated deficit of \$139.3 million.

We expect to incur losses for at least the next several years, primarily due to the expansion of our drug discovery and development efforts, the initiation and continuing conduct of human clinical trials, the launch of new predictive medicine products, the continuation of our internal research and development programs, and expansion of our facilities. We incurred research and development expenses of \$50.7 million, \$47.6 million, and \$36.3 million for the years ended June 30, 2004, 2003, and 2002 respectively. Additionally, we expect to incur substantial sales, marketing and other expenses in connection with building our pharmaceutical and predictive medicine businesses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial.

## **Business Strategy**

We believe that the future of medicine lies in the creation of new classes of drugs that are safer and more effective; drugs that not only treat disease but that also prevent disease from occurring. We also believe that the emerging field of predictive medicine will revolutionize the practice of medicine by identifying and then reducing an individual's risk of developing diseases later in life.

Understanding the cause of disease at the molecular level can be very useful in determining how best to treat the disease. Historically, technologies used to discover pharmaceutical products that treat the symptoms of diseases have been less effective against complex diseases that arise through a combination of genetic and environmental factors, such as cancer and Alzheimer's disease. In order to treat complex diseases effectively, it is imperative to understand how the body uses its genetic information, how the disruption of important biological pathways can lead to disease, and how drugs can be developed to prevent, modify, or halt disease progression. As we learn more about the genetic basis of disease, we believe that we will be able to develop drugs that are safer and more efficacious.

Our business strategy is to understand the relationship between genes, proteins and human diseases in order to develop the next generation of therapeutic and molecular diagnostic products. Through our proprietary technologies, we believe we are uniquely positioned to identify important disease genes, the proteins they produce, and the biological pathways in which they are involved to better understand the underlying molecular basis for the cause of human disease, and to develop novel therapeutic and predictive medicine products. Our business strategy includes the following key elements:

- *Discover important disease genes, understand their function and determine their role in human disease.* We will continue to use our proprietary genomic and proteomic technologies, combined with our bioinformatics and robotic technologies, to efficiently discover important genes and proteins and to understand their role in human disease. These technologies enable us to go beyond a single gene, protein or drug target and explore a large number of potential drug targets involved in a disease pathway. We also use a large array of molecular risk phenotypes to simultaneously screen hundreds of genes against dozens of important diseases. These technologies provide us with significant competitive advantage and numerous product opportunities.
- *Develop and commercialize therapeutic products independently.* We will continue to employ our assay development and high-throughput screening technologies to rapidly identify numerous lead compounds for potential drug development. We intend to take selected drug candidates, particularly in the area of cancer, viral diseases, and Alzheimer's disease, through the clinical development process independently. We are focusing on these indications due to the large

unmet medical need for effective and less toxic drugs, and the oftentimes shorter and less expensive clinical trials resulting from potential fast track review status that the FDA has typically afforded drugs in these areas. Finally, we hope to be able to leverage the expertise of our existing oncology sales force in the marketing of novel cancer therapies.

- *Acquire promising drug candidates and biomarkers/genes from other organizations.* We will continue to take advantage of in-licensing opportunities to augment our in-house product development programs. We recognize that we can't discover everything ourselves and can benefit from the research performed at other organizations. We hope to leverage our financial strength and product development expertise to acquire new product opportunities in our therapeutic and molecular diagnostic areas of focus.
- *Grow and expand our molecular diagnostic business.* We will continue to increase the domestic and foreign market penetration of our existing predictive medicine products and create additional products to capitalize on the emerging areas of predictive medicine. Additionally, we will pursue new products and business opportunities in the area of personalized medicine. Because complex diseases are caused by a variety of different factors and patients have genetic differences, we believe that a single drug won't be effective in all patients. By understanding these different genetic factors, personalized medicine may assist physicians in both selecting the best therapy for a particular patient and prescribing optimal dosage for that patient. Knowing how a patient will respond to particular drugs may decrease the occurrence of adverse side effects of medications while improving their effectiveness.
- *Capitalize on our strategic alliances with major pharmaceutical companies.* We will continue to enter into strategic alliances with large pharmaceutical companies to develop and commercialize novel drug targets and drug candidates in areas outside our primary focus. Ideally, we plan to partner these compounds with major pharmaceutical companies prior to pursuing human clinical trials. This will shift much of the financial risk associated with later stage drug development to our partners, while permitting us to benefit from our partners' drug development expertise and marketing strength.

## **Drug Discovery and Development**

The pharmaceutical industry has been successful in developing medicines to treat the symptoms of disease. However, as the current generation of compounds nears the end of its patent protection, the industry has begun to seek new approaches to disease treatment. We believe that the future of medicine will be in the creation of new drugs that either prevent disease from initially developing or prevent disease from progressing by treating the cause of disease. We are using our broad, proprietary technologies to develop lead compounds and take these drug candidates through human clinical trials. For those therapeutic products in the area of cancer, we would also be able to leverage the marketing efforts of our existing oncology sales force.

We have developed and integrated a powerful set of technologies that enable us to discover genes of commercial importance, elucidate the function of their proteins, and understand their role in disease pathways. Our technology platform provides the knowledge to develop therapeutic products, based on a vastly improved understanding of the genetic basis of disease.

We employ state-of-the-art robotics platforms in all of our high-throughput systems. Each of our robotics systems is connected continually in a real time interface with our proprietary laboratory information management system to maintain a high degree of precision in sample tracking. Our robotics systems have been designed to ensure that the sample volumes used for each of the applications are kept at minimum levels to maintain reagent cost savings in each of our operations.

Our drug discovery and development programs typically involve the following steps:

*Target Discovery.* Target discovery involves identifying novel genes and proteins related to susceptibility, onset or progression of disease. A better understanding of disease has resulted from the identification of disease-related proteins and the subsequent understanding of their function.

Our high-throughput target discovery systems use an integrated instrumentation platform and bioinformatics software custom designed by our scientists and software engineers. We have expanded this system to incorporate the introduction of a large number of genes and research populations, permitting the rapid comparison of novel mutations in genes between individuals with diseases and healthy individuals drawn from the same population. This high-throughput, automated system enables us to rapidly detect genes and proteins that are highly correlated with disease, and in many instances can be shown to be causal.

*Biological Pathway and Protein Function.* Proteins control virtually all cellular processes, including important disease processes. The determination of a protein's function and clarifying the role of a protein in the biological pathway of a disease, leads to the identification of key regulators in that pathway.

Using our high-throughput proteomic technologies, we screen target proteins with our proprietary libraries constructed from a variety of different tissues and organs, such as heart, brain, kidney, liver, breast and prostate. We have constructed proprietary libraries containing approximately 330 million protein fragments. We apply our proprietary automation and robotic capabilities to the protein search process to allow high-throughput processing of protein interactions. Each drug target and its interacting partners form a network, which reads like a map, positioning the target in the disease pathway and tracing the target's role in that pathway.

*Target Validation.* After identifying an important disease-related protein, the drug target must be validated to confirm that it is at a control point in a disease-related pathway and that modulation of the target has a beneficial effect. If through the validation process a protein is not qualified to serve as a drug target, other proteins in the same disease pathway can be examined as potential targets.

We employ RNA interference, dominant negative, and over-expression technologies to validate our drug targets and provide valuable information concerning their function. We are able to gain an important insight into understanding a protein's method of action and function by observing the effects of over expressing or under expressing the protein.

*Assay Development and High-Throughput Screening.* A specific assay must be developed for each validated drug target to identify compounds that inhibit or activate the target. To identify potential drugs, a target is tested through high-throughput screening against a chemically diverse library, comprised of hundreds of thousands of different small molecule compounds. The screening process frequently produces several compounds that interact with the identified drug target.

We have the capability of making cell-based assays, enzyme assays, and assays that identify the disruption of a protein interaction. These proprietary drug-screening technologies allow us to quickly and cost-effectively build high-throughput drug screens using both yeast-based and mammalian-cell systems.

In this type of drug screen when a compound inhibits or activates a protein, a change in the characteristics of the assay is identified. The drug discovery screens are designed to be run in parallel, such that each screen controls for false positives in other screens. The result is greater efficiency and higher screening throughput. Our proprietary compound library contains approximately 300,000 small molecular weight compounds, including over 100,000 patented compounds, specifically constructed to mimic peptides.

Our high-throughput screening is highly automated, using robot workstations and a proprietary computerized management system that monitors each step of the process, confirms that each step has been performed to eliminate operator errors and automatically correlates results with compound identity and drug target. Current capacity is approximately 50 million screening data points per year.

*Lead Optimization.* Compounds that may be suitable for development undergo selection and optimization. These compounds are then optimized by synthesizing and testing a series of closely related compounds. Based on expected activity, safety and bioavailability, the most promising leads in the series are chosen for development.

As we identify compound hits from our proprietary compound library that are active against the drug screening assays, we assess the viability of the hit or lead in terms of its safety, efficacy, and bioavailability. Hits that appear promising move into lead optimization. Our staff of medicinal and analytical chemists develop analogs based on the original lead structure. Our chemists use molecular modeling and other techniques to increase the efficacy, improve the safety, and increase the oral bioavailability of the lead compounds.

To date, we have discovered over 1,000 drug targets and have identified numerous candidate drug compounds from our drug discovery screens, including drug candidates for Alzheimer's disease, cancer, AIDS, and emesis, which satisfy the initial criteria of showing selectivity for one molecular target without obvious toxicity. Furthermore, the compounds have been shown to display good dose response, showing increased activity at higher concentrations and decreased activity at lower concentrations.

*Preclinical Development.* Following optimization, lead compounds enter pre-clinical testing to establish their efficacy and safety in animals. Once a candidate drug has been selected, we assess its safety and efficacy in vivo and perform the necessary toxicology and pharmacokinetic analysis. We have strong in-house capability in the areas of toxicology, pharmacology, formulation, and ADME (absorption, distribution, metabolism, and excretion). If pre-clinical tests are successful, candidate drugs enter clinical trials to determine their efficacy and safety in humans.

*Clinical Development.* New drugs are subject to regulation by the FDA. Following the pre-clinical animal studies, toxicology work and pharmacokinetic analysis, an investigational new drug (IND) application is submitted to the FDA. Clinical trials are normally conducted in three phases to demonstrate safety and efficacy in humans. Our regulatory and clinical staff is experienced in preparing IND applications, performing human clinical trials, and submitting new drug applications (NDA).

## **Therapeutic Products Under Development**

We have 16 drug candidates currently under development in pre-clinical studies. Following is a description of some of our most advanced drug development programs:

*Flurizan™ (R-flurbiprofen): Candidate Drug for Alzheimer's Disease.* This year we completed a phase 1 human clinical trial to establish the safety profile and dosing regimens of Flurizan™ in 48 healthy elderly volunteers. During the phase 1 study, no serious adverse events were observed and no one left the study because of an adverse event. The adverse events reported were mild and non-specific, and there were no significant differences in adverse events between the control volunteers and the Flurizan™ treated volunteers. Flurizan™ appeared to be safe and well tolerated in this healthy older volunteer study. We are currently conducting a phase 2 study in the United Kingdom and Canada which will assess the ability of Flurizan™ to reduce the rate of cognitive decline in approximately 200 patients with mild to moderate Alzheimer's disease. The phase 2 study is expected to be completed during the first calendar quarter of 2005. Alzheimer's disease is a degenerative neurological condition affecting up to 50% of all people aged 85 or older, with an estimated 4 million cases in the United States alone. Current approved treatments, such as acetylcholinesterase inhibitors and NMDA inhibitors, temporarily mitigate symptoms without meaningfully impacting progression of the underlying

disease. Alzheimer's disease is marked by progressive cognitive decline and by the accumulation of amyloid plaques and neurofibrillary tangles in the brain. The major structural component of these plaques is amyloid beta protein, specifically Amyloid beta-42 (A $\beta$ 42). Leading Alzheimer's researchers now believe that A $\beta$ 42 plays an important role in the onset and progression of Alzheimer's disease. Preclinical studies performed at Mayo Clinic Jacksonville and UCSD have demonstrated that R-flurbiprofen substantially lowers the levels of A $\beta$ 42 in both human cell lines and in animal models of Alzheimer's disease. At the 2003 annual meeting of the Society for Neuroscience, data was presented that showed a significant improvement in memory and spatial learning ability in an animal model of Alzheimer's disease. We believe Flurizan™ holds promise as an effective, safe drug for the treatment and prevention of Alzheimer's disease. Four U.S. patents have been awarded on Flurizan™.

*Flurizan™: Candidate Drug for Prostate Cancer.* Flurizan™ is a novel small molecule drug candidate with good oral bioavailability for the treatment of prostate cancer. In animal models of cancer, Flurizan demonstrated marked anti-tumor and anti-metastatic activity, significantly reducing the incidence of primary and secondary prostate tumors. Flurizan™ treated animals experienced a 64% reduced incidence of prostate cancer as compared to the control group and the incidence of metastatic disease was 85% lower in the Flurizan™ treated animals. In humans, the drug was well tolerated in normal healthy subjects and in prostate cancer patients and has completed a phase 2 human clinical trial. Flurizan™ is currently in a phase 2/3 clinical study at 65 centers in the U.S. The study will assess the ability of Flurizan to delay the onset of metastatic cancer in patients with prostate cancer. Approximately 230,000 men in the U.S. will be diagnosed with prostate cancer this year. It is the second leading cause of death from cancer in men. Despite current first-line therapies after diagnosis, cancer cells may remain and can go undetected for years until they develop into metastatic disease. During this stage there is no treatment for these patients who undergo "watchful waiting" by their physician for early signs of cancer recurrence. Our prostate cancer drug candidate, Flurizan™, is designed to address this need and fill this treatment gap. The current clinical study will assess whether the compound is capable of extending the time to metastatic disease and will determine if Flurizan™ holds promise as an effective, safe drug for the treatment of prostate cancer.

*MPI-49839: Candidate Drug for AIDS.* Our novel drug candidate, MPI-49839, represents a new approach to the treatment of AIDS. The unique mechanism behind this drug candidate may enable the creation of an entirely new class of antiviral therapeutics—viral budding inhibitors. The drug is distinct from the protease inhibitors, reverse-transcriptase inhibitors, and fusion inhibitors which are the current generation of AIDS drugs, or integrase inhibitors, which are a new class of anti-HIV drugs being studied. Our anti-HIV drug is particularly exciting in that it has the potential to improve on these current treatments for AIDS through the inhibition of the viral budding mechanism. Our discovery of this viral budding pathway was published in the scientific journal *Cell* on October 5, 2001. With the evolution of multi-drug resistant strains of the virus comes an increased need for therapies that act through different mechanisms. Although current drugs have been quite successful in improving survival for AIDS patients, the drugs do not eliminate the virus, thus drug therapy becomes a life-long commitment. Researchers at the University of California recently estimated that an alarming 42% of HIV-infected individuals will be resistant to the current generation of drugs by 2005. The ability to establish long-term suppression of viral activity requires new drugs that are more impervious to viral resistance. MPI-49839 has been shown in studies to be effective against HIV, including drug resistant strains of HIV. MPI-49839 is a small molecule candidate drug with good oral bioavailability and is in late stage pre-clinical studies. If successful, we plan to enter human clinical trials in AIDS patients.

*MPI-176716: Candidate Drug for Ovarian Cancer.* MPI-176716 is a small molecule drug candidate for IV administration in cancer therapy and is a broad acting inducer of apoptosis. This drug candidate works by disrupting anti-apoptosis protein complexes and has demonstrated broad anti-cancer activity. In xenograph animal models for ovarian cancer, MPI-176716 in combination with carboplatin causes complete tumor remission. While exhibiting strong anti-cancer activity in its own right, MPI-176716

appears to be synergistic with two important classes of chemotherapy drugs, the platins and the taxanes (taxotere). MPI-176716 is not a substrate for multiple drug resistance pumps. This cancer drug candidate is in preclinical testing and if successful will enter human clinical trials next year.

*MPC-6827: Candidate Drug for Cancer.* MPI-6827 is a novel small-molecule drug candidate that inhibits an important step in the pathway controlling apoptosis or programmed cell death. As a result, most dividing cancer cell types tested to date are sensitive to this drug. This drug candidate has strong activity in the low nanomolar range and has demonstrated efficacy against tumors of the prostate, breast, pancreas, colon, and skin (melanoma). According to the American Cancer Society, these cancers are expected to account for over 640,000 new cases in 2004 in the United State alone. We believe that drugs that have the potential to treat a common underlying mechanism of cancer have broad application to the treatment of these diseases and therefore, a large market potential worldwide. MPC-6827 is not a substrate for multiple drug resistance pumps, which is a common problem with many cancer therapies. This cancer drug candidate has good solubility and if final testing is successful we plan to enter human clinical trials in cancer patients next year.

*MPC-4505. Candidate Drug for Chemotherapy Induced Emesis.* MPC-4505 is a small molecule drug candidate with good solubility and good bioavailability. These characteristics of MPC-4505 make it suitable for both an oral formulation and a sterile IV formulation. MPC-4505 is an NK1 receptor antagonist for chemotherapy induced emesis (nausea and vomiting). This drug candidate has good CNS penetration and a long half-life. This drug candidate also has a good safety profile and is in preclinical testing. If successful, we plan to enter human clinical trials in cancer patients.

### **Predictive Medicine Products**

Predictive medicine analyzes genes and their mutations to predict an individual's risk for developing disease and/or their responses to specific treatments. Armed with this risk assessment information, individuals can increase surveillance and take action to prevent or delay the onset of disease. Furthermore, as drugs are developed and approved for use, knowledge about side effects and efficacy in specific individuals emerges. Using this pharmacogenomic knowledge, personal genetic profiles can be developed to predict responses of individuals to drugs. Personalized medicine specifically guides the healthcare management of individuals ensuring that the patient is given the most appropriate therapy and at the optimal dosage.

We are committed to the development and marketing of novel products for the emerging market opportunities of predictive and personalized medicine. We provide educational and support services to physicians and healthcare professionals as part of our predictive medicine business. The predictive medicine products we have developed and currently market are not currently subject to FDA approval, but are subject to oversight and certification under the Clinical Laboratory Improvement Amendments, or CLIA. We have obtained all certifications required by CLIA.

To date we have launched four commercial products. Revenues from our predictive medicine products have cumulatively grown at an annual compound growth rate of over 25 percent since their introduction in 1996. These products include:

*BRACAnalysis®: Predictive Medicine Product for Breast and Ovarian Cancer.* It is estimated that in 2004 there will be approximately 242,000 women in the United States diagnosed with breast or ovarian cancer. This year in the United States, an estimated 57,000 women will die from these cancers. The BRCA1 and BRCA2 genes appear to be responsible for approximately 85% of hereditary breast cancer and approximately 90% of hereditary ovarian cancer. BRACAnalysis® is a comprehensive analysis of the BRCA1 and BRCA2 genes for determining a woman's risk for breast and ovarian cancer. BRACAnalysis® provides important information that we believe will help the patient and her physician make better informed lifestyle, surveillance, preventative medication, and treatment decisions. To

illustrate the value of predictive medicine, it has been shown that pre-symptomatic individuals who carry gene mutations can lower their risk of developing breast and ovarian cancer by more than 50% with appropriate preventive therapies. The price for the test is \$2,975 and is covered by all major health maintenance organizations and health insurance providers in the United States. We own or are the exclusive licensee to 18 U.S. patents covering BRACAnalysis®.

*COLARIS®: Predictive Medicine Product for Colon Cancer and Uterine Cancer.* Colorectal cancer is the second leading cause of cancer deaths in the United States, with approximately 147,000 new cases expected to be diagnosed this year. Familial forms of colorectal cancer were estimated in 1997 to account for 10% to 30% of all cases according to the American Society of Clinical Oncologists. Individuals who carry a deleterious mutation in one of the two colon cancer genes in the COLARIS® test have a greater than 80% lifetime risk of developing colon cancer and women have a 60% lifetime chance of developing uterine cancer. Highly effective preventive measures include colonoscopy and the removal of precancerous polyps. COLARIS® is a comprehensive analysis of the MLH1 and MSH2 genes for determining a person's risk of developing colon cancer or uterine cancer. The price for the test is \$1,950 and is covered by all major health maintenance organizations and health insurance providers in the United States.

*COLARIS AP®: Predictive Medicine Product for Colon Cancer.* COLARIS AP® detects mutations in the APC gene, which cause a colon polyp-forming syndrome known as familial adenomatous polyposis (FAP), and a more common variation of the syndrome known as attenuated FAP (aFAP). Individuals who carry a deleterious mutation in the APC gene have a greater than 80% lifetime risk of developing colon cancer. Effective preventive measures include colonoscopy and the removal of pre-cancerous polyps and preventative surgery. The price for the test is \$1,685 and is covered by all major health maintenance organizations and health insurance providers in the United States. We own or are the exclusive licensee to 6 U.S. patents covering COLARIS AP®.

*MELARIS®: Predictive Medicine Product for Melanoma.* MELARIS®, our fourth predictive medicine product, detects genetic susceptibility to malignant melanoma, a deadly form of skin cancer. Melanoma will affect approximately 55,000 new Americans this year. We discovered that mutations in the p16 gene are involved in cancer and can be inherited to predispose individuals to melanoma, as reported in the September 1994 issue of the journal *Nature Genetics*. Melanoma is lethal within five years in 86% of cases where it has spread to another site in the body. However, when melanoma is diagnosed at an early stage, fewer than 10% of patients die within five years. MELARIS®, which assesses a person's risk of developing melanoma, provides important information that we believe will be useful in the surveillance and prevention of melanoma. Melanoma can be prevented through appropriate screening and a specific threshold of action for mutation carriers, in which pre-cancerous lesions are removed before cancer can develop. The price for the test is \$745 and is covered by some health maintenance organizations and health insurance providers in the United States. We own or are the exclusive licensee to 5 U.S. patents covering MELARIS®.

### **Strategic Alliances**

In order to limit the financial risks associated with the development of certain therapeutic products, including costs associated with related clinical trials of such drugs, in some circumstances our strategy is to enter into alliances with corporate partners who assume such risks and other financial costs. In addition to our current strategic alliances, we are actively pursuing other partners in areas that we believe may enhance our ability to develop and exploit our technology. We have formed strategic alliances with 12 major pharmaceutical or multinational companies including Abbott Laboratories, Bayer Corporation, E.I. du Pont de Nemours and Company (DuPont), Eli Lilly and Company, Hitachi Ltd., Hoffmann-LaRoche Inc., Novartis Corporation, Oracle Corporation, Pfizer, Inc., Schering AG, Schering-Plough Corporation, and Syngenta.

In certain alliances we are dependent on our strategic partners to commercialize the therapeutic products identified under the research collaborations. If our partner commercializes the product, we will receive milestone payments and a royalty on sales of the product or share in the profits derived from sales of the drug. If any of our strategic partners cease efforts to commercialize any therapeutic products identified during our collaboration, the rights to commercialize those products will revert back to us.

### **Patents and Proprietary Rights**

We intend to seek patent protection in the United States and major foreign jurisdictions for genes, proteins, protein interactions, antibodies, drug targets, drug compounds, transgenic animals, technology related methods and processes and other inventions which we believe are patentable and where we believe our interests would be best served by seeking patent protection. We also intend to seek patent protection or rely upon trade secret rights to protect certain other technologies which may be used in discovering and characterizing new genes and proteins and which may be used in the development of novel therapeutic and predictive medicine products. However, any such patents may not issue, and the breadth or the degree of protection of any claims of such patents may not afford us with significant protection. To further protect our trade secrets and other proprietary information, we require that our employees and consultants enter into confidentiality and invention assignment agreements. However, those confidentiality and invention assignment agreements may not provide us with adequate protection.

We own or have licensed rights to 187 issued patents and numerous patent applications in the United States and foreign countries. However, any patent applications which we have filed or will file or to which we have licensed or will license rights may not issue, and patents that do issue may not contain commercially valuable claims. In addition, any patents issued to us or our licensors may not afford meaningful protection for our technology or products or may be subsequently circumvented, invalidated or narrowed.

Our processes and potential products may also conflict with patents which have been or may be granted to competitors, academic institutions or others. As the biotechnology industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to interferences filed by others in the U.S. Patent and Trademark Office, or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the related product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to cease the infringing activity or obtain a license in order to continue to manufacture or market the relevant product or process. We may not prevail in any such action and any license required under any such patent may not be made available on acceptable terms, if at all.

Our failure to obtain a license to any technology that we may require to commercialize our technologies or potential products could have a material adverse effect on our business. There is also considerable pressure on academic institutions to publish discoveries in the genomic and proteomic fields. Such a publication by an academic collaborator of ours prior to the filing date of our application, if it covers a discovery claimed in the application, may preclude the patent from issuing or the filing of foreign patent applications, or if a patent was issued, may invalidate the patent.

We also rely upon unpatented proprietary technology, and in the future may determine in some cases that our interests would be better served by reliance on trade secrets or confidentiality agreements rather than patents or licenses. These include some of our genomic, proteomic, robotic and bioinformatic technologies. We may not be able to protect our rights to such unpatented proprietary technology and others may independently develop substantially equivalent technologies. If we are



unable to obtain strong proprietary rights to our processes or products after obtaining regulatory clearance, competitors may be able to market competing processes and products.

Others may obtain patents having claims which cover aspects of our products or processes which are necessary for or useful to the development, use or manufacture of our services or products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of potential therapeutic products and predictive medicine products could be limited or prohibited.

In addition, we are a party to various license agreements which give us the rights to use certain technology in our research, development and testing processes. We may not be able to continue to license this technology on commercially reasonable terms, if at all. Our failure to maintain rights to this technology could have a material adverse effect on our business.

### **Competition**

Competition is intense in our existing and potential markets. Our competitors in the United States and abroad are numerous and include, among others, major pharmaceutical companies, diagnostic companies, and biotechnology firms, universities and other research institutions. Many of our potential competitors have considerably greater financial, technical, marketing and other resources than we do. We expect competition to intensify in the fields in which we are involved as technical advances occur in these fields and become more widely known.

We expect to encounter significant competition with respect to any drugs that may be developed using our technologies. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of therapeutic products prior to us may achieve a significant competitive advantage. We may not be able to develop such products successfully and we may not obtain patents covering such products that provide protection against competitors. Moreover, competitors may succeed in developing therapeutic products that circumvent our products, and our competitors may succeed in developing technologies or products that are more effective than those developed by us or that would render our technologies or products less competitive or obsolete.

The technologies for discovering genes that predispose persons to major diseases and approaches for commercializing those discoveries are new and rapidly evolving. Rapid technological developments could result in our potential services, products, or processes becoming obsolete before we recover a significant portion of our related research and development costs and associated capital expenditures. If we do not discover additional disease-predisposing genes, characterize their functions, develop predictive medicine products and related information services based on such discoveries, obtain regulatory and other approvals, and launch such services or products before our competitors, we could be adversely affected. Moreover, any predictive medicine products that we may develop could be made obsolete by less expensive or more effective tests or methods that may be developed in the future.

### **Governmental Regulation**

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of our proposed products and services and in our ongoing research and development activities. The therapeutic products and predictive medicine products developed by us will require regulatory approval by governmental agencies prior to commercialization. Various federal statutes and regulations also govern or influence the testing, manufacturing, safety, labeling, storage, record keeping, and marketing of therapeutic products. The process of obtaining these approvals and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial time and financial resources. Any failure by us or our collaborators, licensors or licensees to obtain, or any delay in obtaining regulatory approval could have a material adverse effect on our business.

*Therapeutics.* We intend to develop therapeutic products based on our discoveries. Such products will be subject to regulation by the FDA and foreign regulatory authorities and require approval before they may be clinically tested and commercially marketed for human therapeutic use in the United States and other countries. The precise regulatory requirements with which we will have to comply are undergoing frequent revisions and refinement.

The steps required before a therapeutic product may be marketed in the United States include:

- pre-clinical laboratory, *in vivo*, chemical process development, and formulation studies;
- the submission to the FDA of an Investigational New Drug, or IND, application, which must become effective before human clinical trials may commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for its intended use;
- the submission of a New Drug Application, or NDA, to the FDA; and
- FDA approval of the NDA, including approval of all product labeling and advertising.

The testing and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approvals for any of our products will be granted on a timely basis, if at all.

Human clinical trials are typically conducted in three sequential phases which may overlap:

- PHASE 1: Initial safety study in healthy human subjects or patients where the candidate therapy is tested for safety, dosage tolerance, absorption, distribution, metabolism, and excretion.
- PHASE 2: Studies in a limited patient population designed to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- PHASE 3: Trials are undertaken to further evaluate dosage and clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites.

In the case of products for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers. Since these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 trials and thus these trials are frequently referred to as Phase 1/2 trials. We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of any compound within any specific time period, if at all. Furthermore, the FDA or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a NDA. The FDA may deny a NDA if the applicable regulatory criteria are not satisfied or may require additional data. Even if such data is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval or limit product use if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of the above FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the product or indication. The FDA may grant "fast track" approval for therapies intended to treat severe or life-threatening diseases such as cancer or

AIDS. This policy is intended to facilitate the study of life-saving therapies and shorten the total time for marketing approvals; however, there can be no assurance that these fast track procedures will shorten the time of approval for any of our product candidates. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our or our partners' activities. The FDA or any other regulatory agency may not grant any approvals on a timely basis, if at all. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Delays in obtaining, or failures to obtain regulatory approvals may have a material adverse effect on our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA to assess compliance with current Good Manufacturing Practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with current Good Manufacturing Practices regulations and other FDA regulatory requirements.

*Predictive Medicine.* We are subject to governmental regulation at the federal, state, and local levels as a clinical laboratory. We have received CLIA certification from the Department of Health and Human Services. On the state level, New York has implemented regulations concerning molecular diagnostic testing and we have received approval from the State of New York for breast and ovarian cancer susceptibility, colon and uterine cancer susceptibility, and malignant melanoma susceptibility. We are aware of several other states that require licensing or registration of general clinical laboratory activities. We believe that we have taken all steps required of us in such jurisdictions in order for us to conduct business in those jurisdictions. However, we may not be able to maintain state level regulatory compliance in all states where we may do business. Failure to maintain state regulatory compliance, or changes in state regulatory schemes, could result in a substantial curtailment or even prohibition of our clinical activities and could have a material adverse effect on our business.

CLIA authorizes the Department of Health and Human Services to regulate clinical laboratories. These regulations, which affect us, mandate that all clinical laboratories be certified to perform testing on human specimens and provide specific conditions for certification. These regulations also contain guidelines for the qualification, responsibilities, training, working conditions and oversight of clinical laboratory employees. In addition, specific standards are imposed for each type of test which is performed in a laboratory. CLIA and the regulations promulgated thereunder are enforced through quality inspections of test methods, equipment, instrumentation, materials and supplies on a periodic basis. Any change in CLIA or these regulations or in the interpretation thereof could have a material adverse effect on our business.

Our business is also subject to regulation under state and federal laws regarding environmental protection and hazardous substances control, including the Occupational Safety and Health Act, the Environmental Protection Act, and the Toxic Substance Control Act. We believe that we are in material compliance with these and other applicable laws and that our ongoing compliance will not have a material adverse effect on our business. However, statutes or regulations applicable to our business may be adopted which impose substantial additional costs to assure compliance or otherwise materially adversely affect our operations.

In 1996, Congress passed the Health Insurance Portability and Accountability Act ("HIPAA"). Through this Act, the Department of Health and Human Services ("HHS") is responsible for establishing regulations that are designed to improve the efficiency and effectiveness of the health care system by facilitating the transfer of health information along with protecting the confidentiality and security of health information. Specifically, Title II of HIPAA, the Administrative Simplification Act, contains four provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the health care system and the standardization of data content, codes and formats used in health care transactions. We are currently subject to the HIPAA regulations and maintain an active program designed to address regulatory compliance issues. Penalties for non-compliance with HIPAA include both civil and criminal penalties. Violations could result in civil penalties of up to \$25,000 per type of violation in each calendar year and criminal penalties of up to \$250,000 per violation.

The privacy regulations protect medical records and other personal health information by limiting its use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The deadline for compliance with the privacy regulations was April 14, 2003. In addition to the Federal privacy regulations, there are a number of state laws regarding the confidentiality of health information that are applicable to clinical laboratories. The penalties for violation of state privacy laws may vary widely and new privacy laws in this area are pending. We believe that we have taken all necessary steps required of us to comply with health information privacy and confidentiality statutes and regulations in all jurisdictions, both state and Federal. However, we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, or changes in state or Federal laws regarding privacy, could result in civil and/or criminal penalties and could have a material adverse effect on our business.

On August 17, 2000, HHS published the final version of the transactions and code sets regulations. These regulations adopt standards for eight electronic transactions and for code sets to be used in those transactions. They also contain requirements concerning the use of these standards by health plans, health care clearinghouses, and certain health care providers. The transactions and code sets regulations were designed to improve the overall effectiveness and efficiency of the health care industry by simplifying administration of the system and enabling the efficient electronic transmission of certain health information. The initial compliance date for these regulations was October 16, 2002, but, under the Administrative Simplification Compliance Act, certain covered entities were permitted to file an extension plan with HHS before October 6, 2002 that extended the compliance date to October 16, 2003. We have met the compliance deadline. However, failure to maintain compliance with the transaction and code sets regulations could result in civil and/or criminal penalties and could have a material adverse effect on our business.

The final security regulations were published on February 20, 2003 and require a compliance date of April 21, 2005. The security regulations adopt standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses, and certain health care providers. The security standards were designed by HHS to improve the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information. Our HIPAA security compliance plan has two phases. The first phase involves assessment of our systems, applications and processes for compliance to the security regulations. In the second phase, we will develop a plan to implement remedial measures that must be taken in order to achieve compliance. We are currently assessing our systems, applications and processes for compliance to the security regulations and plan to remediate any affected systems, applications and processes for compliance to the security regulation prior to the April 21, 2005 deadline. We believe the measures required to achieve compliance to the security regulations should not impose significant costs on the company and will be implemented prior to the compliance deadline.

## **Available Information**

We are a Delaware corporation with our principal executive offices located at 320 Wakara Way, Salt Lake City, Utah 84108. Our telephone number is 801.584.3600 and our web site address is [www.myriad.com](http://www.myriad.com). We make available free of charge through the Investor Relations section of our web site our Corporate Code of Conduct and Ethics, as well as our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. We include our web site address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our web site.

## **Human Resources**

As of September 1, 2004, we had 511 full-time equivalent employees, including 70 persons holding doctoral or medical doctor degrees. Most of our employees are engaged directly in research, development, production and marketing activities. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel.

Our employees are not covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

## **Risk Factors**

### **Risks Related to Our Business**

*We are a company in the early stages of development and commercialization and may never achieve the goals of our business plan.*

Although we have developed and marketed several predictive medicine products to date, we believe our future success is dependent upon our ability to successfully develop and commercialize our potential therapeutic products and additional predictive medicine products. Our therapeutic products are still in the early stages of development. We have entered into a phase 2 human clinical trial for the evaluation of Flurizan™, our lead therapeutic compound, for the treatment of Alzheimer's disease. Flurizan™ is also in a large, multi-center phase 2/3 human clinical trial for prostate cancer. Other potential therapeutic products are in various stages of pre-clinical development. Any therapeutic products under development by us will take several more years to develop and undergo extensive pre-clinical and clinical testing. Additionally, therapeutic products are subject to substantial regulatory review. We may be unable to discover or develop any therapeutic or additional predictive medicine products through the utilization of our technologies. Even if we develop products for commercial use, we may not be able to develop products that:

- meet applicable regulatory standards, in a timely manner or at all;
- successfully compete with other technologies and products;
- avoid infringing the proprietary rights of others;
- can be manufactured in sufficient quantities or at reasonable cost; or
- can be successfully marketed.

*We have a history of operating losses and expect to continue to incur losses in the future.*

We have a limited operating history and have experienced operating losses since our inception. We expect these losses to continue for the next several years, and we may never be profitable or achieve significant revenues. For example, we experienced net losses of \$40.6 million, \$24.8 million, and

\$14.0 million for the years ended June 30, 2004, June 30, 2003, and June 30, 2002, respectively. We had an accumulated deficit of \$139.3 million as of June 30, 2004. In order to develop and commercialize our products, we expect to incur significant increases in our expenses over the next several years. As a result, we expect to incur operating losses at least for the foreseeable future. Our ability to achieve significant revenues or profitability will depend upon numerous factors, including our ability to:

- identify drug targets and lead compounds that may lead to future therapeutic products;
- develop candidate drugs and receive required regulatory approvals;
- launch new therapeutic products;
- develop a sales force and marketing team to market our therapeutic products; and
- create and introduce additional marketable predictive medicine products.

***Failure to obtain or maintain regulatory approvals for our potential therapeutic products would harm our business.***

Our potential therapeutic products are subject to stringent regulation with respect to product safety and efficacy by various foreign, federal, state and local authorities. Of particular significance are the FDA's requirements covering R&D, preclinical and clinical testing, manufacturing, quality control, labeling and promotion of drugs for human use. A therapeutic product cannot be marketed in the United States until it has been approved by the FDA, and then can only be marketed for the indications and claims approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application (or NDA), are substantial and can require a number of years. In addition, if any of our potential therapeutic products receive regulatory approval, they would remain subject to ongoing FDA regulation, including, for example, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians and a product recall.

We cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for any of the therapeutic products we are developing or that if approved, we can maintain necessary regulatory approvals for such products, and all of the following could have a material adverse effect on our business:

- significant delays in obtaining or failing to obtain required approvals;
- loss of, or changes to, previously obtained approvals; or
- failure to comply with existing or future regulatory requirements, including Good Manufacturing Practices regulations.

Moreover, it is possible that the current regulatory framework could change or additional regulations could arise at any stage during our product development or marketing, which may affect our ability to obtain or maintain approval of our potential therapeutic products.

***The development and marketing of our potential therapeutic products will be very expensive.***

The development of our potential therapeutic products will require significant research and development expenditures. In addition, preclinical and clinical testing and the regulatory approval process will require the expenditure of significant funds. Before receiving all required FDA approvals to market any therapeutic product, we will have to demonstrate that the product is safe and effective on the patient population and for the diseases that would be treated. The clinical testing, manufacturing and marketing of products are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities, which can take many years and require the expenditure of substantial financial and other resources. Even after spending significant funds, we may

not be able to develop or successfully commercialize any potential therapeutic products as the therapeutic products that we may develop will be subject to the risks of failure inherent in the development of therapeutic products based on new technologies. These risks include the possibilities that:

- potential therapeutic products will be found to be unsafe or ineffective or otherwise fail to receive necessary regulatory clearances;
- the products, if safe and effective, will be difficult to manufacture on a large scale or uneconomical to market;
- proprietary rights of third parties will preclude us or our partners from marketing our products; or
- third parties will market superior or equivalent products.

In addition, as we develop therapeutic products internally, we will have to make significant investments in therapeutic product development, marketing, sales and regulatory compliance resources. We will also have to establish facilities for or contract for the manufacture of products, including supplies of drugs used in clinical trials, under the current Good Manufacturing Practices of the FDA, which can be time consuming and costly.

*We have only limited experience in regulatory affairs, and some of our products may be based on new technologies, which may delay or otherwise adversely affect our ability to obtain necessary regulatory approvals.*

We have only limited experience in filing the applications necessary to gain regulatory approvals. Moreover, certain of our potential therapeutic products are based on new technologies and new therapeutic approaches that have not been extensively tested in humans. The regulatory requirements governing these types of products may be more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with any products that we develop based on these new technologies or new therapeutic approaches.

*We face uncertain results of clinical trials for our potential therapeutic products.*

Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential therapeutic products. The completion rate of clinical trials depends significantly upon the rate of patient enrollment. Our inability to enroll patients on a timely basis could result in increased expenses and product development delays, which could harm our business. We can make no assurances that patients enrolled in our clinical trials will respond to our product candidates, that any product candidate will be safe and effective or that data derived from the trials will be suitable for submission to the FDA or satisfactorily support a NDA. Factors that affect patient enrollment include:

- size of patient population for the targeted disease;
- eligibility criteria;
- proximity of eligible patients to clinical sites;
- clinical trial protocols;
- the existence of competing protocols and existing approved drugs; and
- level of patient access provided by physicians.

Even if a trial is fully enrolled, significant uncertainties remain as to whether it will prove successful. Success in preclinical development and early clinical trials does not ensure that large-scale

trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. A number of companies in the pharmaceutical and biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause that trial to be redone or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be redone or terminated.

Furthermore, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and may be difficult to predict. Failure to comply with extensive FDA regulations may result in delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. The FDA may also suspend our clinical trials at any time if it concludes that the participants are being exposed to unacceptable risks. Consequently, we cannot ensure that clinical testing will be completed timely or successfully, if at all, for any of our potential therapeutic products.

***We have limited experience in conducting preclinical studies and clinical trials, which may delay or prevent us from commercializing our therapeutic products.***

We currently have limited experience in conducting preclinical and clinical trial activities. We may choose to, or may be required to, suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements or the clinical trials are not well designed. In order to successfully develop and commercialize our therapeutic products, we will be required to further develop our internal capability to conduct preclinical studies and clinical trials. For some of our drug candidates, we may rely on our strategic partners, and in some instances, we may rely on third-party clinical research organizations, to design and conduct preclinical and clinical activities. Our reliance on strategic partners and third parties for preclinical and clinical development activities will reduce our control over these activities. In addition, if necessary, our inability to contract for any necessary clinical activities on acceptable terms would impair or delay our ability to complete our drug development programs, which could adversely affect our business.

***Our current predictive medicine products and other predictive medicine or therapeutic products that we may develop may never achieve significant commercial market acceptance.***

We may not succeed in achieving significant commercial market acceptance of any of our products. While we have marketed several of our predictive medicine products for several years and have gained some acceptance with oncologists, we need to convince the larger group of obstetricians/gynecologists and primary care physicians of the benefits of our predictive medicine products in order to increase our sales of those products. Our ability to successfully commercialize our current predictive medicine products, as well as any other predictive medicine or therapeutic products that we may develop, will depend on several factors, including:

- Our ability to convince the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products and predictive medicine products.
- The agreement by third-party payors to provide full or even partial reimbursement coverage for our products, the scope and extent of which will affect patients willingness or ability to pay for our products and will likely heavily influence physicians' decisions to recommend our products.
- The willingness of physicians and patients to utilize predictive medicine products which are difficult to perform and interpret. This difficulty is caused by a combination of factors, including the large number, sometimes many hundreds, of different mutations in the genes which our tests analyze, the need to characterize each specific mutation, and the ability of our products to



predict only as to a statistical probability, not certainty, that a tested individual will develop the disease for which the test has been completed.

These factors present obstacles to significant commercial acceptance of our products, which we will have to spend substantial time and money to overcome, if we can do so at all. Our inability to successfully do so will harm our business.

*If we are unable to comply with applicable governmental regulations, we may not be able to continue our predictive medicine operations.*

The establishment and operation of our predictive medicine laboratory and the production and marketing of services and products developed through our technologies, as well as our ongoing research and development activities, are subject to regulation by numerous federal, state and local governmental authorities in the United States. We have been accredited under the Clinical Laboratory Evaluation Program by the Department of Health of the State of New York. Failure to maintain state regulatory compliance, or changes in state regulatory schemes, could result in a substantial curtailment or even prohibition of our clinical activities and could have a material adverse effect on our business. We have received federal accreditation from the Department of Health and Human Services under the Clinical Laboratory Improvement Amendments, or CLIA, to operate our predictive medicine laboratory. However, our accreditation may subsequently be revoked, suspended or limited, or our accreditation may not be renewed on an annual basis as required. Furthermore, while the FDA has elected not to substantially regulate the activities or tests performed by laboratories like our clinical laboratory, the FDA has stated that it has the right to do so, and the FDA may seek to regulate or require clearance or approval of our products in the future. If the FDA should require that these products receive FDA approval prior to their use in our laboratory, this approval may not be received on a timely basis, if at all.

*If we do not compete effectively with scientific and commercial competitors, we may not be able to successfully commercialize our products.*

The biotechnology research field is intense and highly competitive. This research is characterized by rapid technological change. Our competitors in the United States and abroad are numerous and include, among others, major pharmaceutical companies, diagnostic companies, biotechnology firms, universities and other research institutions. Many of our potential competitors have considerably greater financial, technical, marketing and other resources than we do, which may allow these competitors to discover important genes and determine their function before we do. We could be adversely affected if we do not discover genes, proteins or protein pathways and characterize their function, develop therapeutic and predictive medicine products based on these discoveries, obtain regulatory and other approvals and launch these products and their related services before our competitors. We also expect to encounter significant competition with respect to any therapeutic or predictive medicine products that we may develop or commercialize. Those companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of therapeutic products before we do may achieve a significant competitive advantage in marketing and commercializing their products. We may not be able to develop therapeutic or predictive medicine products successfully and may not obtain patents covering these products that provide protection against our competitors. Moreover, our competitors may succeed in developing therapeutic or predictive medicine products that circumvent our technologies or products. Furthermore, our competitors may succeed in developing technologies or products that are more effective than those developed by us or that would render our technologies or products less competitive or obsolete. We expect competition to intensify in the fields in which we are involved as technical advances in these fields occur and become more widely known.

***If we are unable to maintain relationships with current collaborative partners or enter into new collaborative arrangements, then our business could be harmed.***

Part of our current business strategy is to form collaborative arrangements with strategic partners to develop and commercialize therapeutic products in the therapeutic areas outside of our primary focus areas of cancer, infectious disease, and Alzheimer's disease. We currently depend and will depend in the future on third parties for support in product development, manufacturing, marketing and distribution. We may not be able to maintain our current collaborative arrangements or negotiate additional acceptable collaborative arrangements in the future.

Any current or future collaborative arrangement may not be successful. Failure of any collaborative arrangement, or termination by any of our collaborative partners of their respective agreements, could have a material adverse effect on our business. Further, additional milestone payments and future potential royalty payments from our collaborators are dependent upon their continuing to develop products based on the potential therapeutic targets we delivered to them. These partners may decide not to develop any products based on these targets. Even if these partners commence such development, they could decide to terminate it at any time.

In addition, our collaborative partners may pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means of developing diagnostic products or treatments for the diseases targeted by our collaborative programs. Our interests may not continue to coincide with those of our collaborative partners, and some of our collaborative partners may develop, independently or with third parties, therapeutic or diagnostic products that could compete with those developed in collaboration with our partners or independently. Additionally, disputes over rights or technology or other proprietary interests may arise. Such disputes or disagreements between us and our collaborative partners could lead to delays in collaborative research projects, or could result in litigation or arbitration, any of which could have a material adverse effect on our business.

***If our current research collaborators or scientific advisors terminate their relationships with us or develop relationships with a competitor, our ability to discover genes, proteins and drug targets, and commercialize therapeutic and predictive medicine products could be adversely affected.***

We have relationships with research collaborators at academic and other institutions who conduct research at our request. These research collaborators are not our employees. As a result, we have limited control over their activities and, except as otherwise required by our collaboration agreements, can expect only limited amounts of their time to be dedicated to our activities. Our ability to discover genes, proteins, and protein pathways involved in human disease and commercialize therapeutic and predictive medicine products will depend in part on the continuation of these collaborations. If any of these collaborations are terminated, we may not be able to enter into other acceptable collaborations. In addition, our existing collaborations may not be successful.

Our research collaborators and scientific advisors may have relationships with other commercial entities, some of which could compete with us. Our research collaborators and scientific advisors sign agreements which provide for the confidentiality of our proprietary information and the results of studies conducted at our request. We may not, however, be able to maintain the confidentiality of our technology and other confidential information in connection with every collaboration. The dissemination of our confidential information could have a material adverse effect on our business.

*If our current operating plan changes and we find that our existing capital resources will not meet our needs, we may find it necessary to raise additional funding, which funding may not be available.*

We anticipate that our existing capital resources will enable us to maintain currently planned operations for at least the next two years. However, we base this expectation on our current operating plan, which may change. We have incurred, and will continue to incur, significant costs in the discovery, development and marketing of current and prospective therapeutic and predictive medicine products. Our ongoing drug discovery programs and our efforts to develop therapeutic and predictive medicine products will require substantial cash resources. If, for example, we discover a new drug target with promising therapeutic properties, we would require funding in addition to our current operating plan to move the candidate drug into pre-clinical studies and human clinical trials. Additionally, if a new disease gene is discovered through these efforts, we would require funds in addition to our current operating plan to demonstrate clinical utility and develop and launch a new predictive medicine product. If, due to changes in our current operating plan, adequate funds are not available, we may be required to raise additional funds. Sources of potential additional capital resources may include, but are not limited to, public or private equity financings, establishing a credit facility, or selling convertible debt securities. This additional funding, if necessary, may not be available to us on reasonable terms, or at all.

Because of our potential long-term capital requirements, we may access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We have an effective shelf registration on file with the SEC pursuant to which up to \$139.7 million of our securities remain available for sale at our discretion, subject to certain limitations under federal securities laws and the rules of the Nasdaq Stock Market. If additional funds are raised by issuing equity securities, existing shareholders may suffer significant dilution.

*If we are not able to protect our proprietary technology, our business will be harmed and we may not remain competitive.*

Our success will depend, in part, on our ability to obtain patent protection, both in the United States and in other countries, for drug targets we discover, for therapeutic compounds we develop, for predisposing genes we identify and related technologies, processes, methods and other inventions that we believe are patentable. Our ability to preserve our trade secrets and other intellectual property is also critical to our long-term success. The patent position of biotechnology firms generally is highly uncertain and involves complex legal and factual questions. To date there has not emerged from the United States Patent and Trademark Office, or PTO, the United States courts, or from patent offices or courts in foreign countries, a consistent policy regarding the breadth of claims allowed in biotechnology patents. Our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technology or products. In addition, any patents issued to us or our licensors may be challenged, and subsequently narrowed, invalidated or circumvented.

If a third party files a patent application with claims to a drug target, gene or protein we have discovered, the PTO may declare an interference between competing patent applications. If an interference is declared, we may not prevail in the interference. If the other party prevails in the interference, we may be precluded from commercializing services or products based on the drug target, gene or protein, or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

We also rely upon unpatented proprietary technologies. Although we require employees, consultants and collaborators to sign confidentiality agreements, we may not be able to adequately protect our rights in such unpatented proprietary technologies, which could have a material adverse effect on our business. For example, others may independently develop substantially equivalent

proprietary information or techniques or otherwise gain access to our proprietary technologies or disclose our technologies to our competitors.

***If we were sued for patent infringement by third parties, we might incur significant costs and delays in product introduction.***

Our products may also conflict with patents that have been or may be granted to others. Our industry includes many organizations seeking to rapidly identify drug targets, small molecule compounds, proteins, and genes through the use of genomic, proteomic and other technologies. To the extent any patents are issued to those organizations on drug targets, proteins, genes or uses for such genes and proteins, the risk increases that the sale of our predictive medicine products currently being marketed or under development, and any sales of therapeutic drugs developed by us, may give rise to claims of patent infringement. Others may have filed and in the future are likely to file patent applications covering genes or drug targets that are similar or identical to our products. Any of these patent applications may have priority over our patent applications and these entities or persons could bring legal proceedings against us seeking damages or seeking to enjoin us from testing, manufacturing or marketing our products. Patent litigation is costly, and even if we prevail, the cost of such litigation could have a material adverse effect on us. If the other parties in any such actions are successful, in addition to any liability for damages, we could be required to cease the infringing activity or obtain a license. Any license required may not be available to us on commercially acceptable terms, if at all. Our failure to obtain a license to any technology that we may require to commercialize our products could have a material adverse effect on our business. We believe that there may be significant litigation in the industry regarding patent and other intellectual property rights. If we become involved in this litigation, it could consume a substantial portion of our managerial and financial resources.

***If we fail to retain our key personnel and hire, train and retain qualified employees and consultants, we may not be able to successfully continue our business.***

Because of the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified management, scientific and technical personnel. We are currently recruiting additional qualified management, scientific and technical personnel. Competition for such personnel is intense. Loss of the services of or failure to recruit additional key management, scientific and technical personnel would adversely affect our research and development programs and predictive medicine business and may have a material adverse effect on our business as a whole.

Our agreements with our employees generally provide for employment that can be terminated by either party without cause at any time, subject to specified notice requirements. Further, the non-competition provision to which each employee is subject expires on the applicable date of termination of employment.

***We have no experience manufacturing therapeutic products, and we currently intend to rely on third-party manufacturers to manufacture such products for us.***

We have no manufacturing experience and no commercial scale manufacturing capabilities for therapeutic products. We currently rely upon third parties to produce material for preclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties, including our collaborators, for the commercial production of approved therapeutic products. There are a limited number of manufacturers that operate under the FDA's current Good Manufacturing Practices regulations. If we are unable to arrange for third party manufacturing of our products, or to do so on commercially reasonable terms, our clinical trials may be delayed, or we may not be able to complete development of our therapeutic products or market them.

Reliance on third party manufacturers also entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us. Although we have no current intention to do so, if in the future we elected to manufacture certain of our therapeutic products in our own manufacturing facilities, we would need to invest substantial additional funds and recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

*We have limited sales, marketing and distribution capabilities, and with respect to our potential therapeutic products, we may be dependent on third parties to successfully perform these functions on our behalf, or we may be required to incur significant costs and devote significant efforts to augment our existing capabilities.*

We have limited sales, marketing and distribution experience and capabilities. These capabilities consist primarily of our sales force that markets our cancer-related predictive medicine products to oncologists in the United States. We believe that if we develop therapeutic products in the area of cancer, given the concentrated nature of the oncology market, we would be able to leverage the efforts of our existing oncology sales force to market these products. However, depending on the nature of the therapeutic products and services for which we obtain marketing approval, we may need to rely significantly on sales, marketing and distribution arrangements with our collaborators and other third parties. For example, some types of pharmaceutical products require a large sales force and extensive marketing capabilities for effective commercialization. For therapeutic products for diseases with small medical specialty groups, such as AIDS or Alzheimer's disease, we may elect to develop our own sales and marketing force. If in the future we elect to perform sales, marketing and distribution functions for such types of products ourselves, we would face a number of additional risks, including the need to recruit a large number of additional experienced marketing and sales personnel.

*We depend on a limited number of third parties for some of our supplies of equipment and reagents. If these supplies become unavailable, then we may not be able to successfully perform our research or operate our business at all or on a timely basis.*

We currently rely on a small number of suppliers to provide our gene sequencing machines and reagents required in connection with our research. We believe that currently there are limited alternative suppliers of gene sequencing machines and reagents. The gene sequencing machines or the reagents may not remain available in commercial quantities at acceptable costs. If we are unable to obtain when needed additional gene sequencing machines or an adequate supply of reagents or other ingredients at commercially reasonable rates, our ability to continue to identify genes and perform molecular diagnostic testing would be adversely affected.

*If we were successfully sued for product liability, we could face substantial liabilities that exceed our resources.*

Our business exposes us to potential liability risks inherent in the testing, marketing and processing of predictive medicine products, including possible misdiagnoses. In addition, clinical trials or marketing of any potential therapeutic products may expose us to liability claims from the use of these therapeutic products. Although we are insured against such risks in amounts that we believe to be commercially reasonable, our present product liability insurance may be inadequate. A successful product liability claim in excess of our insurance coverage could have a material adverse effect on our business. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products.

***Our business involves environmental risks that may result in liability for us.***

In connection with our research and development activities, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens, chemicals and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Although we believe that our safety procedures for handling and disposing of controlled materials comply with the standards prescribed by state and federal regulations, accidental contamination or injury from these materials may occur. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

**Risks Related to Our Common Stock**

***Our stock price is highly volatile, and our stock may lose all or a significant part of its value.***

The market prices for securities of biotechnology and genomic companies have been volatile. This volatility has significantly affected the market prices for these securities for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price for our common stock has fluctuated significantly since public trading commenced in October 1995, and it is likely that the market price will continue to fluctuate in the future. In the two years ended June 30, 2004, our stock price has ranged from \$8.43 per share to \$26.20 per share. In addition, the stock market has experienced extreme price and volume fluctuations. Events or factors that may have a significant impact on our business and on the market price of our common stock include the following:

- quarterly fluctuations in operating results;
- announcements by us, our collaborative partners or our present or potential competitors;
- technological innovations or new commercial products or services;
- research or product development results;
- regulatory approval developments;
- developments or disputes concerning patent or proprietary rights;
- public concern regarding the safety, efficacy or other implications of our products or services; or
- general market conditions out of our control.

***Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and our stockholders' rights plan, or poison pill, could make a third-party acquisition of us difficult.***

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the General Corporation Law of Delaware, which prohibits us from engaging in certain business combinations, unless the business combination is approved in a prescribed manner. In addition, our restated certificate of incorporation and restated bylaws also contain certain provisions that may make a third-party acquisition of us difficult, including:

- a classified board of directors, with three classes of directors each serving a staggered three-year term;
- the ability of the board of directors to issue preferred stock;

- a 70% super-majority shareholder vote to amend our bylaws and certain provisions of our certificate of incorporation; and
- the inability of our stockholders to call a special meeting or act by written consent.

We also have implemented a stockholders' rights plan, also called a poison pill, which could make it uneconomical for a third party to acquire our company on a hostile basis. These provisions, as well as Section 203, may discourage certain types of transactions in which our stockholders might otherwise receive a premium for their shares over then current market price, and may limit the ability of our stockholders to approve transactions that they think may be in their best interests.

## **Item 2. FACILITIES**

Our headquarters and facilities are located in Salt Lake City, Utah. We currently lease a 149,000 square foot building dedicated to research and development, administration and laboratory space that has received federal certification under CLIA. Activity related to our research, drug development and predictive medicine segments is performed at this location. The lease on our facility has a term of fifteen years, through March 2016, and provides for a renewal option for a term of up to ten additional years.

We believe that our existing facilities and equipment are well maintained and in good working condition. We believe our current facilities will provide adequate capacity for the foreseeable future. We continue to make investments in capital equipment as needed to meet the research requirements of our collaborative agreements, our drug development requirements, and the anticipated demand for our predictive medicine products.

## **Item 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

## **Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended June 30, 2004.

## PART II

### Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### Market Information

Our Common Stock began trading on the Nasdaq National Market on October 6, 1995 under the symbol "MYGN". The following table sets forth, for the last two fiscal years, the high and low sales prices for the Common Stock, as reported by the Nasdaq National Market, during the periods indicated:

	<u>High</u>	<u>Low</u>
<b>Fiscal 2004:</b>		
Fourth Quarter .....	\$19.50	\$13.57
Third Quarter .....	\$18.52	\$12.95
Second Quarter .....	\$13.45	\$11.00
First Quarter .....	\$16.50	\$10.88
<b>Fiscal 2003:</b>		
Fourth Quarter .....	\$18.40	\$10.01
Third Quarter .....	\$16.32	\$ 8.43
Second Quarter .....	\$21.64	\$13.37
First Quarter .....	\$26.20	\$12.44

As of September 1, 2004, there were approximately 183 stockholders of record of our Common Stock and, according to our estimates, approximately 13,431 beneficial owners of the Common Stock.

#### Dividends

We have not paid dividends to our stockholders since our inception and we do not plan to pay cash dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance our growth.

#### Sale of Unregistered Securities

None.



## Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated financial data and has been derived from our audited consolidated financial statements. Consolidated balance sheets as June 30, 2004 and 2003, as well as consolidated statements of operations for the years ended June 30, 2004, 2003, and 2002 and the report thereon are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with the audited consolidated financial statements (and notes thereon) and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in Item 7.

In thousands, except per share amounts	Years Ended June 30,				
	2004	2003	2002	2001	2000
<b>Consolidated Statement of Operations Data:</b>					
Predictive medicine revenue . . . . .	\$ 43,294	\$ 34,683	\$ 26,821	\$ 17,091	\$ 8,793
Research revenue . . . . .	11,748	27,822	27,015	28,071	25,220
Related party research revenue . . . . .	1,606	1,816	—	—	—
Total research revenue . . . . .	13,354	29,638	27,015	28,071	25,220
Total revenues . . . . .	56,648	64,321	53,836	45,162	34,013
Costs and expenses:					
Predictive medicine cost of revenue . . . . .	13,751	12,553	10,717	7,403	3,986
Research and development expense . . . . .	50,697	47,589	36,295	33,818	28,099
Selling, general and administrative expense . . . . .	34,835	31,525	25,484	17,078	13,475
Total costs and expenses . . . . .	99,283	91,667	72,496	58,299	45,560
Operating loss . . . . .	(42,635)	(27,346)	(18,660)	(13,137)	(11,547)
Other income (expense):					
Interest income . . . . .	2,025	2,900	5,385	6,851	3,208
Other . . . . .	(10)	38	(214)	(305)	(383)
Loss before income taxes . . . . .	(40,620)	(24,408)	(13,489)	(6,591)	(8,722)
Income taxes . . . . .	—	417	500	583	—
Net loss . . . . .	<u>\$(40,620)</u>	<u>\$(24,825)</u>	<u>\$(13,989)</u>	<u>\$ (7,174)</u>	<u>\$ (8,722)</u>
Basic and diluted net loss per share . . . . .	<u>\$ (1.49)</u>	<u>\$ (0.96)</u>	<u>\$ (0.59)</u>	<u>\$ (0.31)</u>	<u>\$ (0.43)</u>
Basic and diluted weighted average shares outstanding . . . . .	<u>27,326</u>	<u>25,730</u>	<u>23,660</u>	<u>22,815</u>	<u>20,220</u>
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investment securities . . . . .	\$141,839	\$126,292	\$124,243	\$145,955	\$ 88,656
Working capital . . . . .	122,113	83,486	56,834	104,615	57,263
Total assets . . . . .	188,356	182,823	157,390	172,145	106,375
Stockholders' equity . . . . .	173,276	163,486	128,869	139,561	77,707

# Quarterly Financial Data (Unaudited)

In thousands, except per share amounts	Quarters Ended			
	June 30, 2004	March 31, 2004	December 31, 2003*	September 30, 2003
<b>Consolidated Statement of Operations Data:</b>				
Predictive medicine revenue	\$ 13,085	\$ 11,699	\$ 10,446	\$ 8,064
Research revenue	1,987	1,909	2,773	5,079
Related party research revenue	—	148	929	529
Total research revenue	1,987	2,057	3,702	5,608
Total revenues	15,072	13,756	14,148	13,672
Costs and expenses:				
Predictive medicine cost of revenue	3,835	3,709	3,448	2,758
Research and development expense	12,004	12,390	13,329	12,974
Selling, general and administrative expense	10,154	8,821	7,752	8,108
Total costs and expenses	25,993	24,920	24,529	23,840
Operating loss	(10,921)	(11,164)	(10,381)	(10,168)
Other income (expense):				
Interest income	456	473	527	569
Other	5	(5)	—	(10)
	461	468	527	559
Net loss	\$(10,460)	\$(10,696)	\$ (9,854)	\$(9,609)
Basic and diluted net loss per share	\$ (0.37)	\$ (0.39)	\$ (0.36)	\$ (0.35)
Basic and diluted weighted average shares outstanding	27,967	27,148	27,109	27,087

In thousands, except per share amounts	Quarters Ended			
	June 30, 2003	March 31, 2003	December 31, 2002	September 30, 2002
<b>Consolidated Statement of Operations Data:</b>				
Predictive medicine revenue	\$ 9,354	\$ 9,314	\$ 8,151	\$ 7,864
Research revenue	5,971	6,432	8,406	7,015
Related party research revenue	380	342	462	632
Total research revenue	6,351	6,774	8,868	7,647
Total revenues	15,705	16,088	17,019	15,511
Costs and expenses:				
Predictive medicine cost of revenue	3,277	3,361	2,995	2,921
Research and development expense	13,372	11,053	12,218	10,946
Selling, general and administrative expense	6,729	7,785	9,295	7,716
Total costs and expenses	23,378	22,199	24,508	21,583
Operating loss	(7,673)	(6,111)	(7,489)	(6,072)
Other income (expense):				
Interest income	631	701	725	842
Other	3	1	(5)	39
Loss before income taxes	(7,039)	(5,409)	(6,769)	(5,191)
Income taxes	42	125	125	125
Net loss	\$(7,081)	\$(5,534)	\$(6,894)	\$(5,316)
Basic and diluted net loss per share	\$ (0.26)	\$ (0.20)	\$ (0.27)	\$ (0.22)
Basic and diluted weighted average shares outstanding	27,041	27,012	25,081	23,827

\* Certain balances have been reclassified to reflect subsequent final settlement of legal dispute.

## **Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Overview**

We are a leading biopharmaceutical company focused on the development and marketing of novel therapeutic and molecular diagnostic products. We employ a number of proprietary technologies that permit us to understand the genetic basis of human disease and the role that genes and their related proteins play in the onset and progression of disease. We use this information to guide the development of new healthcare products that treat major diseases and assess a person's risk of disease later in life.

We have devoted substantially all of our resources to undertaking our drug discovery and development programs, operating our predictive medicine business, and continuing our research and development efforts. We have three reportable operating segments: (i) research, (ii) predictive medicine, and (iii) drug development. See Note 8 "Segment and Related Information" in the notes to our consolidated financial statements for information regarding these operating segments. Our revenues have consisted primarily of sales of predictive medicine products and research payments. We have yet to attain profitability and, for year ended June 30, 2004, we had a net loss of \$40.6 million. As of June 30, 2004 we had an accumulated deficit of \$139.3 million.

We expect to incur losses for at least the next several years, primarily due to the expansion of our drug discovery and development efforts, the initiation and continuing conduct of human clinical trials, the launch of new predictive medicine products, the continuation of our internal research and development programs, and expansion of our facilities. Additionally, we expect to incur substantial sales, marketing and other expenses in connection with building our pharmaceutical and predictive medicine businesses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial.

### **Critical Accounting Policies**

Critical accounting policies are those policies which are both important to the portrayal of a company's financial condition and results and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are as follows:

- revenue recognition;
- allowance for doubtful accounts; and
- investments in privately-held companies.

*Revenue Recognition.* Research revenues include revenues from research agreements, milestone payments, and technology licensing agreements. In applying the principles of SAB 104 to research and technology license agreements we consider the terms and conditions of each agreement separately to arrive at a proportional performance methodology of recognizing revenue. Such methodologies involve recognizing revenue on a straight-line basis over the term of the agreement and based on costs incurred relative to the total estimated contract costs (cost-to-cost method). We make adjustments, if necessary, to the estimates used in our cost-to-cost calculations as work progresses and we gain experience. The principal costs under these agreements are for personnel expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from our estimates. Payments received on uncompleted long-term contracts may be greater than or less than incurred costs and estimated earnings and have been recorded as other receivables or deferred revenues in the accompanying consolidated balance sheets. We recognize revenue from milestone payments as

agreed-upon events representing the achievement of substantive steps in the development process are achieved and where the amount of the milestone payments approximates the value of achieving the milestone. We recognize revenue from up-front nonrefundable license fees on a straight-line basis over the period of our continued involvement in the research and development project.

Predictive medicine revenues include revenues from the sale of predictive medicine products and related marketing agreements. Predictive medicine revenue is recognized upon completion of the test and communication of results. Up-front payments related to marketing agreements are recognized ratably over the life of the agreement.

*Allowance for Doubtful Accounts.* The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amount of assets at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Trade accounts receivable are comprised of amounts due from sales of our predictive medicine products. We analyze trade accounts receivable and consider historic experience, customer creditworthiness, facts and circumstances specific to outstanding balances, and payment term changes when evaluating the adequacy of the allowance for doubtful accounts. Changes in these factors could result in material adjustments to the expense recognized for bad debt.

*Investments in Privately-Held Companies.* We review the valuation of our investments in privately-held biotechnology and pharmaceutical companies for possible impairment as changes in facts and circumstances indicate that impairment should be assessed. The amount of impairment, if any, and valuation of these investments are based on our estimates and, in certain circumstances, the completion of independent, third-party appraisals of the investments. Inherent in these estimates and appraisals are assumptions such as the comparability of the investee to similar publicly traded companies, the value of the investee's underlying research and development efforts, the likelihood that the investee's current research projects will result in a marketable product, and the investee's expected future cash flows. Accordingly, the amount recognized by us upon ultimate liquidation of these investments may vary significantly from the estimated fair values at June 30, 2004.

#### **Recent Accounting Pronouncements**

In December 2003, the FASB issued a revision to Interpretation No. 46, *Consolidation of Variable Interest Entities* (FIN46R). FIN46R clarifies the application of ARB No. 51, *Consolidated Financial Statements* to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. FIN46R requires the consolidation of these entities, known as variable interest entities, by the primary beneficiary of the entity. The primary beneficiary is the entity, if any, that will absorb a majority of the entity's expected losses, receive a majority of the entity's expected residual returns, or both.

Among other changes, the revisions of FIN46R (a) clarified some requirements of the original FIN46, which had been issued in January 2003, (b) eased some implementation problems, and (c) added new scope exceptions. FIN46R deferred the effective date of the Interpretation for public companies, to the end of the first reporting period ending after March 15, 2004. The adoption of this interpretation did not have a material effect on our business, results of operations, financial position, or liquidity.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. This statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The adoption of this statement did not have a material effect on our business, results of operations, financial position, or liquidity.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* (SFAS 150). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. The adoption of this statement did not have a material effect on our business, results of operations, financial position, or liquidity.

In November 2002, the EITF reached a consensus on EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables* (Issue No. 00-21). In applying Issue No. 00-21, separate contracts with the same entity or related parties that are entered into at or near the same time are presumed to have been negotiated as a package and should, therefore, be evaluated as a single arrangement in considering whether there are one or more units of accounting. That presumption may be overcome if there is sufficient evidence to the contrary. Issue No. 00-21 also addresses how arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The adoption of this issue did not have a material effect on our business, results of operations, financial position, or liquidity.

## **Results of Operations**

### *Years ended June 30, 2004 and 2003*

Predictive medicine revenues for the fiscal year ended June 30, 2004 were \$43.3 million compared to \$34.7 million for the prior fiscal year, an increase of 25%. Predictive medicine revenue is comprised primarily of sales of predictive medicine products, and also includes some marketing fees and (forensic) DNA analysis fees. Increased sales and marketing efforts, coupled with recent publications concerning the clinical utility of our products have resulted in wider acceptance of our products by the medical community and increased revenues for the fiscal year ended June 30, 2004. There can be no assurance that predictive medicine revenues will continue to increase at historical rates.

Total research revenues for the fiscal year ended June 30, 2004 were \$13.4 million compared to \$29.6 million for the prior fiscal year. Related party research revenues included in total research revenues for the fiscal year ended June 30, 2004 and 2003 were \$1.6 million and \$1.8 million, respectively. Related party research revenue is comprised of certain research services performed for Prolexys Pharmaceuticals, Inc., which is 49% owned by us. The agreement to provide these research services was terminated effective January 26, 2004. Research revenues are comprised of research payments received pursuant to collaborative agreements, amortization of upfront technology license fees and milestone payments. This 55% decrease in total research revenue is primarily attributable to the successful completion of two of our research collaborations with corporate partners. Research revenue from our research collaboration agreements is recognized using a proportional performance methodology. Consequently, as these programs progress and costs increase or decrease, revenues may increase or decrease proportionately.

Predictive medicine cost of revenue for the fiscal year ended June 30, 2004 was \$13.8 million compared to \$12.6 million for the prior fiscal year. This increase of 10% in predictive medicine cost of revenue is primarily due to the 25% increase in predictive medicine revenues for the fiscal year ended June 30, 2004 compared to the prior fiscal year. This increase was partially offset by technology improvements and efficiency gains in the operation of our predictive medicine business. Our technology and efficiency improvements also contributed to an increase in our gross profit margin, which was 68% for the fiscal year ended June 30, 2004 compared to 64% for the prior fiscal year. There can be no assurance that predictive medicine gross profit margins will continue to increase at historical rates.

Research and development expenses for the fiscal year ended June 30, 2004 were \$50.7 million compared to \$47.6 million for the prior fiscal year. This increase of 7% was primarily due to increased

costs associated with our ongoing clinical trials in Alzheimer's disease and prostate cancer, increases in our other drug discovery and drug development programs, the settlement of claims resulting from a dispute with a third party, and increases in internally-funded research programs. These increases added approximately \$14.1 million to our research and development expenses for the fiscal year ended June 30, 2004 compared to the prior fiscal year. These increases were partially offset by the completion of two of our research collaborations, which resulted in decreased research and development expenses of approximately \$11.0 million for the fiscal year ended June 30, 2004 compared to the prior fiscal year. We expect our research and development expenses to continue to fluctuate based on changes in our research programs and the progression of our drug development programs.

Selling, general and administrative expenses for the fiscal year ended June 30, 2004 were \$34.8 million compared to \$31.5 million for the prior fiscal year. Selling, general and administrative expenses consist primarily of salaries, commissions and related personnel costs for sales, marketing, executive, legal, finance, accounting, human resources, business development, allocated facilities expenses and other corporate expenses. This increase of 11% was primarily attributable to general increases in costs to support growth in our predictive medicine business and therapeutic development efforts. Increases in salaries and benefits, facilities costs, bad debt, legal, and other costs resulted in an increase of approximately \$6.4 million to our selling, general, and administrative expense for the fiscal year ended June 30, 2004 compared to the prior fiscal year. These increases were partially offset by reduced marketing costs from our direct-to-consumer advertising campaign conducted in the prior fiscal year, resulting in a decrease of approximately \$3.1 million to our selling, general, and administrative expense for the fiscal year ended June 30, 2004 compared to the prior fiscal year. We expect our selling, general and administrative expenses will continue to fluctuate depending on the number and scope of new product launches and our drug discovery and drug development efforts.

#### *Years ended June 30, 2003 and 2002*

Predictive medicine revenue for our fiscal year ended June 30, 2003 was \$34.7 million compared to \$26.8 million for the prior fiscal year, an increase of 29%. Increased sales and marketing efforts and wider acceptance of our products by the medical community resulted in increased revenues for the year ended June 30, 2003. However, there can be no assurance that predictive medicine revenue will continue to increase at historical rates.

Total research revenue for our fiscal year ended June 30, 2003 was \$29.6 million compared to \$27.0 million for the prior fiscal year. Related party research revenue included in total research revenue for the fiscal years ended June 30, 2003 and 2002 were \$1.8 million and \$0, respectively. Related party research revenue is comprised of certain scientific outsourcing services performed for Prolexys Pharmaceuticals, Inc., which is 49% owned by us. This increase of 10% in total research revenue is primarily attributable to revenue recognized from our DuPont and Abbott Laboratories collaborations, including a \$1 million milestone recognized and received from Abbott Laboratories for the discovery of a gene involved in depression. Research revenue from our research collaboration agreements is recognized using a proportional performance methodology. Consequently, as these programs progress and costs increase or decrease, revenues may increase or decrease proportionately.

Predictive medicine cost of revenue for our fiscal year ended June 30, 2003 was \$12.6 million compared to \$10.7 million for the prior fiscal year. This increase of 17% in predictive medicine cost of revenue is primarily due to the 29% increase in predictive medicine revenue for the fiscal year ended June 30, 2003 compared to prior fiscal year. Gross margin percent for the fiscal year ended June 30, 2003 was 64% compared to 60% for the prior fiscal year. This increase in gross margin percent resulted from technology improvements and gains in efficiencies in the operations of our predictive medicine business.

Research and development expenses for our fiscal year ended June 30, 2003 were \$47.6 million compared to \$36.3 million for the prior fiscal year. This increase of 31% was primarily due to increased costs associated with our ongoing clinical trials in prostate cancer and Alzheimer's disease, other drug development programs, and increased research efforts associated with our Dupont collaboration. These increases added approximately \$22.7 million to our research and development expenses for the fiscal year ended June 30, 2003. These increases were partially offset by the completion of several research collaborations and changes to internally funded research programs, which resulted in decreased research and development expenses of approximately \$11.4 million for the fiscal year ended June 30, 2003.

Selling, general and administrative expenses for our fiscal year ended June 30, 2003 were \$31.5 million compared to \$25.5 million for the prior fiscal year. This increase of 24% was attributable to marketing costs related to our direct-to-consumer campaign, which resulted in an increase of approximately \$3.1 million to our selling, general and administrative expense for the fiscal year ended June 30, 2003. Additionally, general increases in personnel and costs related to the support of our predictive medicine business and drug development efforts resulted in increases of approximately \$2.9 million to our selling, general, and administrative expenses for the fiscal year ended June 30, 2003. We expect our selling, general and administrative expenses will continue to fluctuate depending on the number and scope of new product launches and our drug discovery and drug development efforts.

### **Liquidity and Capital Resources**

Cash, cash equivalents, and marketable investment securities increased \$15.5 million or 12% from \$126.3 million at June 30, 2003 to \$141.8 million at June 30, 2004. This increase in cash, cash equivalents, and marketable investment securities is primarily attributable to the public offering of \$50.1 million (net proceeds) of our common stock in June 2004. This increase was partially offset by capital expenditures for research equipment, increased expenditures for our ongoing clinical trials, internal drug development programs and other expenditures incurred in the ordinary course of business. As a result of changes in interest rates and cash, cash equivalents, and marketable investment securities, interest income for the fiscal year ended June 30, 2004 was \$2.0 million compared to \$2.9 million for the prior fiscal year, a decrease of 30%.

Net cash used in operating activities was \$30.9 million during the fiscal year ended June 30, 2004 compared to \$46.5 million used in operating activities during the prior fiscal year. Trade receivables increased \$3.1 million between June 30, 2003 and June 30, 2004, primarily due to the 25% increase in predictive medicine sales during the same period. Other receivables decreased \$8.7 million between June 30, 2003 and June 30, 2004, primarily due to the collection of amounts receivable for research performed under our research collaboration agreements. Accounts payable decreased by \$3.5 million between June 30, 2003 and June 30, 2004, primarily as a result of payments made for purchases of equipment and lab supplies. Deferred revenue, representing the difference in collaborative payments received and research revenue recognized, decreased by \$1.8 million between June 30, 2003 and June 30, 2004 due to the completion of two of our research collaborations.

Our investing activities provided cash of \$1.9 million during the fiscal year ended June 30, 2004 and used cash of \$12.0 million during the prior fiscal year. Investing activities were comprised primarily of changes to marketable investment securities and capital expenditures for research equipment.

Financing activities provided cash of \$51.3 million during the fiscal year ended June 30, 2004 and provided cash of \$59.0 million in the prior fiscal year. In June 2004 we received \$50.1 million in net proceeds from an underwritten offering of 3.4 million shares of our common stock pursuant to our outstanding shelf registration statement on Form S-3 (Registration No. 333-73124). Morgan Stanley & Co. Incorporated served as the sole underwriter of the offering. Following the offering we have approximately \$139.7 million of securities available for sale under the shelf registration statement.

During the fiscal year ended June 30, 2004 additional funds were received from the exercise of stock options.

We believe that with our existing capital resources, we will have adequate funds to maintain our current and planned operations for at least the next two years, although no assurance can be given that changes will not occur that would consume available capital resources before such time. Our future capital requirements, cash flows, and results of operations could be affected by and will depend on many factors, including:

- the progress of our preclinical and clinical activities;
- the progress of our research and development programs;
- the progress of our drug discovery and drug development programs;
- the cost of developing and launching additional predictive medicine products;
- the costs of filing, prosecuting and enforcing patent claims;
- the costs associated with competing technological and market developments;
- the costs associated with potential litigation;
- the payments received under collaborative agreements and changes in collaborative research relationships;
- the costs associated with potential commercialization of our discoveries, if any, including the development of manufacturing, marketing and sales capabilities; and
- the cost and availability of third-party financing for capital expenditures and administrative and legal expenses.

Because of our significant long-term capital requirements, we intend to raise funds when conditions are favorable, even if we do not have an immediate need for additional capital at such time.

### Contractual Obligations

The following table represents our consolidated contractual obligations as of June 30, 2004 (in thousands):

	<u>Total</u>	<u>Less than one year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>More than 5 years</u>
Operating leases . . . . .	\$24,358	3,123	7,774	2,212	11,249
Contractual services . . . . .	10,631	8,731	1,900	—	—
Purchase commitments . . . . .	165	165	—	—	—
Total . . . . .	\$35,154	12,019	9,674	2,211	11,250

Contractual services represent financial commitments for drug development and clinical trial activities that can be terminated at our request. The expected timing of payment for the obligations listed above is estimated based on current information. Actual payment timing and amounts may differ depending on the timing of goods or services received or other changes.

### Effects of Inflation

We do not believe that inflation has had a material impact on our business, sales, or operating results during the periods presented.



## **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We maintain an investment portfolio in accordance with our Investment Policy. The primary objectives of our Investment Policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our Investment Policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment.

Our investments consist of securities of various types and maturities of three years or less, with a maximum average maturity of 12 months. These securities are classified as available-for-sale. Available-for-sale securities are recorded on the balance sheet at fair market value with unrealized gains or losses reported as part of accumulated other comprehensive income/loss. Gains and losses on investment security transactions are reported on the specific-identification method. Dividend and interest income are recognized when earned. A decline in the market value of any available-for-sale security below cost that is deemed other than temporary results in a charge to earnings and establishes a new cost basis for the security.

The securities held in our investment portfolio are subject to interest rate risk. Changes in interest rates affect the fair market value of the marketable investment securities. After a review of our marketable securities as of June 30, 2004, we have determined that in the event of a hypothetical ten percent increase in interest rates, the resulting decrease in fair market value of our marketable investment securities would be insignificant to the consolidated financial statements as a whole.

### **Certain Factors That May Affect Future Results of Operations**

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Annual Report contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, among other things: our inability to further identify, develop and achieve commercial success for new products and technologies; our ability to discover drugs that are safer and more efficacious; our ability to develop predictive medicine products that help determine which patients are subject to greater risk of developing diseases and who would therefore benefit from new preventive therapies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that we may be unable to successfully finance and secure regulatory approval of and market our drug candidates; our dependence upon pharmaceutical and biotechnology collaborations; the levels and timing of payments under our collaborative agreements; uncertainties about our ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development of competing products and services; our ability to protect our proprietary technologies; patent-infringement claims; risks of new, changing and competitive technologies and regulations in the United States and internationally; and other factors discussed under the heading "Risk Factors" contained in Item 1 of this Annual Report.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only of the date of this Annual Report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

## Item 8. FINANCIAL STATEMENTS

### MYRIAD GENETICS, INC. Index to Financial Statements

	Number
Report of Independent Registered Public Accounting Firm .....	F-1
Consolidated Balance Sheets as of June 30, 2004 and 2003 .....	F-2
Consolidated Statements of Operations for the Years Ended June 30, 2004, 2003 and 2002 .....	F-3
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the Years Ended June 30, 2004, 2003 and 2002 .....	F-4
Consolidated Statements of Cash Flows for the Years Ended June 30, 2004, 2003 and 2002 .....	F-5
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## Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

### Item 9A. CONTROLS AND PROCEDURES

- (a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective to ensure that material information relating to us, including our consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Annual Report on Form 10-K was being prepared.

In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

- (b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Myriad Genetics, Inc.:

We have audited the accompanying consolidated balance sheets of Myriad Genetics, Inc. and subsidiaries as of June 30, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended June 30, 2004. In connection with our audits of the consolidated financial statements, we have also audited the accompanying consolidated financial statement schedule. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Myriad Genetics, Inc. and subsidiaries as of June 30, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2004, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

KPMG, LLP

Salt Lake City, Utah  
September 2, 2004

**MYRIAD GENETICS, INC.  
AND SUBSIDIARIES**

Consolidated Balance Sheets

June 30, 2004 and 2003

(In thousands, except per share amounts)

	<u>2004</u>	<u>2003</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 83,983	61,603
Marketable investment securities . . . . .	31,383	11,172
Prepaid expenses . . . . .	7,279	7,740
Trade accounts receivable, less allowance for doubtful accounts of \$1,205 in 2004 and \$895 in 2003 . . . . .	13,994	12,917
Other receivables . . . . .	554	9,241
Related party receivables . . . . .	—	150
Total current assets . . . . .	<u>137,193</u>	<u>102,823</u>
Equipment and leasehold improvements:		
Equipment . . . . .	34,212	31,826
Leasehold improvements . . . . .	7,692	7,531
	41,904	39,357
Less accumulated depreciation and amortization . . . . .	24,565	20,675
Net equipment and leasehold improvements . . . . .	<u>17,339</u>	<u>18,682</u>
Long-term marketable investment securities . . . . .	26,473	53,517
Other assets . . . . .	7,351	7,801
	<u>\$ 188,356</u>	<u>182,823</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 7,938	11,454
Accrued liabilities . . . . .	5,933	4,925
Deferred revenue . . . . .	1,209	2,958
Total current liabilities . . . . .	<u>15,080</u>	<u>19,337</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value. Authorized 5,000 shares; no shares issued and outstanding . . . . .	—	—
Common stock, \$0.01 par value. Authorized 60,000 shares; issued and outstanding 30,623 shares in 2004 and 27,079 shares in 2003 . . . . .	306	271
Additional paid-in capital . . . . .	312,453	261,155
Accumulated other comprehensive income (loss) . . . . .	(212)	711
Accumulated deficit . . . . .	(139,271)	(98,651)
Total stockholders' equity . . . . .	<u>173,276</u>	<u>163,486</u>
	<u>\$ 188,356</u>	<u>182,823</u>

See accompanying notes to consolidated financial statements.

**MYRIAD GENETICS, INC.  
AND SUBSIDIARIES**

Consolidated Statements of Operations  
Years ended June 30, 2004, 2003, and 2002  
(In thousands, except per share amounts)

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Predictive medicine revenue .....	\$ 43,294	34,683	26,821
Research revenue .....	11,748	27,822	27,015
Related party research revenue .....	1,606	1,816	—
Total research revenue .....	<u>13,354</u>	<u>29,638</u>	<u>27,015</u>
Total revenues .....	56,648	64,321	53,836
Costs and expenses:			
Predictive medicine cost of revenue .....	13,751	12,553	10,717
Research and development expense .....	50,697	47,589	36,295
Selling, general, and administrative expense .....	<u>34,835</u>	<u>31,525</u>	<u>25,484</u>
Total costs and expenses .....	<u>99,283</u>	<u>91,667</u>	<u>72,496</u>
Operating loss .....	(42,635)	(27,346)	(18,660)
Other income (expense):			
Interest income .....	2,025	2,900	5,385
Other .....	<u>(10)</u>	<u>38</u>	<u>(214)</u>
Loss before income taxes .....	(40,620)	(24,408)	(13,489)
Income taxes .....	<u>—</u>	<u>417</u>	<u>500</u>
Net loss .....	<u><u>\$(40,620)</u></u>	<u><u>(24,825)</u></u>	<u><u>(13,989)</u></u>
Basic and diluted loss per common share .....	\$ (1.49)	(0.96)	(0.59)
Basic and diluted weighted average shares outstanding .....	27,326	25,730	23,660

See accompanying notes to consolidated financial statements.

**MYRIAD GENETICS, INC.  
AND SUBSIDIARIES**

Consolidated Statements of Stockholders' Equity and Comprehensive Loss

Years ended June 30, 2004, 2003, and 2002

(In thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Comprehensive income (loss)	Stockholders' equity
	Shares	Amount					
Balances at June 30, 2001 . . . . .	23,442	\$234	198,800	364	(59,837)		139,561
Issuance of common stock for cash . . . . .	375	4	3,349	—	—	—	3,353
Net loss . . . . .	—	—	—	—	(13,989)	(13,989)	(13,989)
Unrealized gains (losses) on marketable investment securities:							
Unrealized holding losses arising during period . . . . .	—	—	—	—	—	(64)	—
Less classification adjustment for gains included in net loss . . . . .	—	—	—	—	—	8	—
Other comprehensive loss . . . . .	—	—	—	(56)	—	(56)	(56)
Comprehensive loss . . . . .	—	—	—	—	—	\$ (14,045)	—
Balances at June 30, 2002 . . . . .	23,817	238	202,149	308	(73,826)		128,869
Issuance of common stock for cash upon exercise of options and warrants . . . . .	262	3	1,895	—	—	—	1,898
Issuance of common stock for cash, net of offering costs of \$159 . . . . .	3,000	30	57,111	—	—	—	57,141
Net loss . . . . .	—	—	—	—	(24,825)	(24,825)	(24,825)
Unrealized gains (losses) on marketable investment securities:							
Unrealized holding gains arising during period . . . . .	—	—	—	—	—	370	—
Less classification adjustment for gains included in net loss . . . . .	—	—	—	—	—	33	—
Other comprehensive income . . . . .	—	—	—	403	—	403	403
Comprehensive loss . . . . .	—	—	—	—	—	\$ (24,422)	—
Balances at June 30, 2003 . . . . .	27,079	271	261,155	711	(98,651)		163,486
Issuance of common stock for cash upon exercise of options . . . . .	144	1	1,237	—	—	—	1,238
Issuance of common stock for cash, net of offering costs of \$55 . . . . .	3,400	34	50,061	—	—	—	50,095
Net loss . . . . .	—	—	—	—	(40,620)	(40,620)	(40,620)
Unrealized gains (losses) on marketable investment securities:							
Unrealized holding losses arising during period . . . . .	—	—	—	—	—	(923)	—
Less classification adjustment for gains included in net loss . . . . .	—	—	—	—	—	—	—
Other comprehensive loss . . . . .	—	—	—	(923)	—	(923)	(923)
Comprehensive loss . . . . .	—	—	—	—	—	\$ (41,543)	—
Balances at June 30, 2004 . . . . .	<u>30,623</u>	<u>\$306</u>	<u>312,453</u>	<u>(212)</u>	<u>(139,271)</u>		<u>173,276</u>

See accompanying notes to consolidated financial statements.

**MYRIAD GENETICS, INC.  
AND SUBSIDIARIES**

Consolidated Statements of Cash Flows  
Years ended June 30, 2004, 2003, and 2002  
(In thousands)

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:			
Net loss	\$(40,620)	(24,825)	(13,989)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,766	5,275	4,496
Loss (gain) on disposition/impairment of assets	10	(5)	222
Gain on sale of investment securities	—	(33)	(8)
Bad debt expense	2,020	564	405
Changes in operating assets and liabilities:			
Prepaid expenses	461	(2,913)	(763)
Trade receivables	(3,097)	(6,248)	(3,849)
Other receivables	8,687	(9,021)	95
Related party receivables	150	(150)	1,811
Other assets	—	—	(670)
Accounts payable	(3,516)	1,992	(196)
Accrued liabilities	1,008	1,334	509
Related party payable	—	(1,038)	1,038
Deferred revenue	(1,749)	(11,472)	(5,413)
Net cash used in operating activities	<u>(30,880)</u>	<u>(46,540)</u>	<u>(16,312)</u>
Cash flows from investing activities:			
Capital expenditures	(3,883)	(8,036)	(6,853)
Investments in other companies	—	—	(2,482)
Proceeds from sale of investments in other companies	—	—	630
Increase in other assets	(100)	(2,850)	—
Purchases of investment securities held-to-maturity	—	—	(8,514)
Maturities of investment securities held-to-maturity	—	4,752	14,123
Purchases of investment securities available-for-sale	(52,730)	(51,784)	(81,243)
Maturities/sales of investment securities available-for-sale	58,640	45,955	122,428
Net cash provided by (used in) investing activities	<u>1,927</u>	<u>(11,963)</u>	<u>38,089</u>
Cash flows from financing activities:			
Net proceeds from issuance of common stock	51,333	59,039	3,353
Net cash provided by financing activities	<u>51,333</u>	<u>59,039</u>	<u>3,353</u>
Net increase in cash and cash equivalents	22,380	536	25,130
Cash and cash equivalents at beginning of year	61,603	61,067	35,937
Cash and cash equivalents at end of year	<u>\$ 83,983</u>	<u>61,603</u>	<u>61,067</u>
Supplemental disclosures of noncash investing and financing activities:			
Fair value adjustment on marketable investment securities charged to stockholders' equity	\$ (923)	403	(56)

See accompanying notes to consolidated financial statements.



**MYRIAD GENETICS, INC.  
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Notes to Consolidated Financial Statements

June 30, 2004 and 2003

**(1) Organization and Summary of Significant Accounting Policies**

***(a) Organization and Business Description***

Myriad Genetics, Inc. and subsidiaries (collectively, the Company) is a leading biopharmaceutical company focused on the development and marketing of novel therapeutic and molecular diagnostic products. The Company employs a number of proprietary technologies that permit it to understand the genetic basis of human disease and the role that genes and their related proteins play in the onset and progression of disease. The Company uses this information to guide the development of new healthcare products that treat major diseases and assess a person's risk of disease later in life. The Company's operations are located in Salt Lake City, Utah.

***(b) Principles of Consolidation***

The consolidated financial statements presented herein include the accounts of Myriad Genetics, Inc. and its wholly owned subsidiaries, Myriad Genetic Laboratories, Inc., Myriad Pharmaceuticals, Inc., and Myriad Financial, Inc. All intercompany amounts have been eliminated in consolidation.

***(c) Cash Equivalents***

Cash equivalents of \$72.7 million and \$48.6 million at June 30, 2004 and 2003, respectively, consist of short-term securities. The Company considers all highly liquid debt instruments with maturities at date of purchase of 90 days or less to be cash equivalents.

***(d) Equipment and Leasehold Improvements***

Equipment and leasehold improvements are stated at cost. Depreciation and amortization are computed using the straight-line method based on the lesser of estimated useful lives of the related assets or lease terms. Equipment items have depreciable lives from five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful lives or the associated lease terms, which range from three to ten years.

***(e) Impairment of Long-Lived Assets***

The Company accounts for long-lived assets in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. This Statement requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

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June 30, 2004 and 2003

**(f) *Income Taxes***

Income taxes are recorded using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

**(g) *Revenue Recognition***

The Company applies the provisions of Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) to all of its revenue transactions.

Research revenues include revenues from research agreements, milestone payments, and technology licensing agreements. In applying the principles of SAB 104 to research and technology license agreements the Company considers the terms and conditions of each agreement separately to arrive at a proportional performance methodology of recognizing revenue. Such methodologies involve recognizing revenue on a straight-line basis over the term of the agreement and based on costs incurred relative to the total estimated contract costs (cost-to-cost method). The Company makes adjustments, if necessary, to the estimates used in its cost-to-cost calculations as work progresses and the Company gains experience. The principal costs under these agreements are for personnel expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from our estimates. Payments received on uncompleted long-term contracts may be greater than or less than incurred costs and estimated earnings and have been recorded as other receivables or deferred revenues in the accompanying consolidated balance sheets. The Company recognizes revenue from milestone payments as agreed-upon events representing the achievement of substantive steps in the development process are achieved and where the amount of the milestone payments approximates the value of achieving the milestone. The Company recognizes revenue from up-front nonrefundable license fees on a straight-line basis over the period of the Company's continued involvement in the research and development project.

Predictive medicine revenues include revenues from the sale of predictive medicine products and related marketing agreements. Predictive medicine revenue is recognized upon completion of the test and communication of results. Payments received in advance of predictive medicine work performed are recorded as deferred revenue. Up-front payments related to marketing agreements are recognized ratably over the life of the agreement.

**(h) *Net Loss per Common and Common Equivalent Share***

Net loss per common share is computed based on the weighted average number of common shares and, as appropriate, dilutive potential common shares outstanding during the period. Stock options and warrants are considered to be potential common shares.

**MYRIAD GENETICS, INC.  
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Notes to Consolidated Financial Statements (Continued)

June 30, 2004 and 2003

Basic loss per common share is the amount of loss for the period available to each share of common stock outstanding during the reporting period. Diluted loss per share is the amount of loss for the period available to each share of common stock outstanding during the reporting period and to each share that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares outstanding during the period.

In calculating loss per common share the net loss and the weighted average common shares outstanding were the same for both the basic and diluted calculation.

For the years ended June 30, 2004, 2003, and 2002, there were antidilutive potential common shares of 5,899,252, 4,922,144, and 4,176,135, respectively. Accordingly, these potential common shares were not included in the computation of diluted loss per share for the years presented, but may be dilutive to future basic and diluted earnings per share.

**(i) Use of Estimates**

Management of the Company has made a number of estimates and assumptions relating to the reporting of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

**(j) Marketable Investment Securities**

The Company accounts for marketable investment securities by grouping them into one of two categories: held-to-maturity or available-for-sale. Held-to-maturity securities are those securities that the Company has the ability and intent to hold until maturity. All other securities are classified as available-for-sale.

Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Available-for-sale securities are recorded at fair value. Unrealized holding gains and losses, net of the related tax effect, on available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders' equity until realized.

Gains and losses on investment security transactions are reported on the specific-identification method. Dividend and interest income are recognized when earned. A decline in the market value of any available-for-sale or held-to-maturity security below cost that is deemed other than temporary results in a charge to earnings and establishes a new cost basis for the security. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective-interest method.

**(k) Fair Value Disclosure**

At June 30, 2004, the consolidated financial statements' carrying amount of the Company's financial instruments approximates fair value.

**(l) Stock-Based Compensation**

The Company has adopted the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) and SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, an amendment of SFAS 123. SFAS 123 permits

**MYRIAD GENETICS, INC.  
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Notes to Consolidated Financial Statements (Continued)

June 30, 2004 and 2003

entities to adopt a fair-value-based method of accounting for stock options or similar equity instruments. However, it also allows an entity to continue measuring compensation cost for stock-based compensation using the intrinsic-value method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). The Company has elected to continue to apply the provisions of APB 25 and provide pro forma disclosures required by SFAS 123. As such, no stock-based employee compensation cost is reflected in net loss, as all options granted under these plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in thousands except per share amounts):

	Years ended June 30		
	2004	2003	2002
Net loss, as reported . . . . .	\$40,620	24,825	13,989
Deduct total stock-based employee compensation expense determined under fair value based method for all awards, net of tax related effects . . . . .	25,105	25,532	21,078
Pro forma net loss . . . . .	<u>\$65,725</u>	<u>50,357</u>	<u>35,067</u>
Loss per share:			
Basic and diluted—as reported . . . . .	\$ 1.49	0.96	0.59
Basic and diluted—pro forma . . . . .	2.41	1.96	1.48

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants in 2004, 2003, and 2002, respectively: risk-free interest rates of 3.2%, 3.0%, and 4.3%; expected dividend yields of 0% for all years; expected lives of 6.0 years, 6.0 years, and 6.0 years; and expected volatility of 59%, 71%, and 82%.

**(m) Other Assets**

Other assets are comprised of purchased intellectual property, investments in privately held biotechnology and pharmaceutical companies, and a purchased library of chemical compounds. The private biotechnology and pharmaceutical company investments are both accounted for under the cost method. Management reviews the valuation of these investments for possible impairment as changes in facts and circumstances indicate that impairment should be assessed. For the year ended June 30, 2004, the valuation of these investments was based on management's estimates and the completion of an independent, third-party appraisal. Accordingly, the amount recognized by the Company upon the ultimate liquidation of these investments may vary significantly from the estimated fair value at June 30, 2004. The library of chemical compounds and related purchased intellectual property are being amortized ratably over the expected useful life of five years.

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Notes to Consolidated Financial Statements (Continued)

June 30, 2004 and 2003

**(n) Trade Receivables and Allowance for Doubtful Accounts**

Trade accounts receivable are comprised of amounts due from sales of the Company's predictive medicine products and are recorded at the invoiced amount, net of discounts and allowances. The allowance for doubtful accounts is based on the Company's best estimate of the amount of probable losses in the Company's existing accounts receivable, which is based on historical write-off experience. Account balances are charged against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The Company does not have any off-balance-sheet credit exposure related to its customers.

**(o) Reclassifications**

Certain amounts in the 2003 and 2002 consolidated financial statements have been reclassified to conform to the 2004 presentation.

**(2) Marketable Investment Securities**

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value for available-for-sale securities by major security type and class of security at June 30, 2004 and 2003 were as follows (in thousands):

	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Fair value
At June 30, 2004:				
Available-for-sale:				
Corporate bonds and notes . . . . .	\$22,257	30	(67)	22,220
Commercial paper . . . . .	3,981	1	(1)	3,981
Federal agency issues . . . . .	19,390	4	(113)	19,281
Tax auction securities . . . . .	750	—	—	750
Euro dollar bonds . . . . .	11,690	6	(72)	11,624
	<u>\$58,068</u>	<u>41</u>	<u>(253)</u>	<u>57,856</u>
At June 30, 2003:				
Available-for-sale:				
Corporate bonds and notes . . . . .	\$43,336	596	(17)	43,915
Federal agency issues . . . . .	10,699	20	(1)	10,718
Tax auction securities . . . . .	2,500	—	—	2,500
Euro dollar bonds . . . . .	7,443	113	—	7,556
	<u>\$63,978</u>	<u>729</u>	<u>(18)</u>	<u>64,689</u>

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Notes to Consolidated Financial Statements (Continued)

June 30, 2004 and 2003

Maturities of debt securities classified as available-for-sale are as follows at June 30, 2004 (in thousands):

	Amortized cost	Fair value
Available-for-sale:		
Due within one year . . . . .	\$31,415	31,383
Due after one year through three years . . . . .	26,653	26,473
	<u>\$58,068</u>	<u>57,856</u>

All securities in an unrealized loss position as of June 30, 2004 are debt securities. Debt securities in an unrealized loss position as of June 30, 2004 were not impaired at acquisition and the decline in fair value is due to interest rate fluctuations. Debt securities available for sale in an unrealized loss position as of June 30, 2004 are summarized as follows (in thousands):

	Less than 12 months		More than 12 months		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
Debt Securities:						
Corporate bonds and notes . . . . .	\$10,804	(45)	2,047	(22)	12,851	(67)
Commercial paper . . . . .	998	(1)	—	—	998	(1)
Federal agency issues . . . . .	14,745	(113)	—	—	14,745	(113)
Euro dollar bonds . . . . .	6,655	(72)	—	—	6,655	(72)
	<u>\$33,202</u>	<u>(231)</u>	<u>2,047</u>	<u>(22)</u>	<u>35,249</u>	<u>(253)</u>

**(3) Leases**

The Company leases office and laboratory space under three noncancelable operating leases. Future minimum lease payments under these leases as of June 30, 2004 are as follows (in thousands):

Fiscal year ending:	
2005 . . . . .	\$ 3,123
2006 . . . . .	3,123
2007 . . . . .	2,439
2008 . . . . .	2,212
2009 . . . . .	2,212
Thereafter . . . . .	11,249
	<u>\$24,358</u>

Rental expense was \$4.0 million in 2004, \$4.9 million in 2003, and \$4.6 million in 2002.

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**(4) Stock-Based Compensation**

In 2003 the Company adopted the 2003 Employee, Director and Consultant Stock Option Plan (the "2003 Plan"). The Company has reserved 1,300,000 shares of common stock for issuance upon the exercise of options that the Company plans to grant from time to time under this plan. Furthermore, additional shares represented by options previously granted under the Company's 2002 Amended and Restated Employee, Director and Consultant Stock Option Plan (the "2002 Plan") which are canceled or expire after the date of stockholder approval of the 2003 Plan without delivery of shares of stock by the Company and any shares which have been reserved but not granted under the 2002 Plan as of the date of stockholder approval of the Plan are available for grant under the 2003 Plan.

The exercise price of options granted in 2004, 2003, and 2002 was equivalent to the fair market value of the stock at the date of grant. The number of shares, terms, and exercise period are determined by the board of directors on an option-by-option basis. Options generally vest ratably over four or five years and expire ten years from the date of grant. As of June 30, 2004, 1,005,065 shares are reserved for future grant under the 2003 Plan.

A summary of activity is as follows:

	2004		2003		2002	
	Number of shares	Weighted average exercise price	Number of shares	Weighted average exercise price	Number of shares	Weighted average exercise price
Options outstanding at beginning of year . . . . .	4,892,144	\$31.29	4,110,635	\$34.94	4,055,561	\$34.03
Plus options granted . . . . .	1,296,875	14.43	1,257,100	17.34	825,764	39.00
Less:						
Options exercised . . . . .	(44,675)	6.29	(167,903)	4.30	(344,073)	7.40
Options canceled or expired . . . . .	(275,092)	36.19	(307,688)	37.81	(426,617)	56.34
Options outstanding at end of year . . . . .	<u>5,869,252</u>	27.53	<u>4,892,144</u>	31.29	<u>4,110,635</u>	34.94
Options exercisable at end of year . . . . .	3,102,658	31.52	2,203,456	31.09	1,526,064	25.45
Weighted average fair value of options granted during the year . . . . .		8.25		11.39		28.23

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June 30, 2004 and 2003

The following table summarizes information about fixed stock options outstanding at June 30, 2004:

Range of exercise prices	Options outstanding			Options exercisable	
	Number outstanding at June 30, 2004	Weighted average remaining contractual life (years)	Weighted average exercise price	Number exercisable at June 30, 2004	Weighted average exercise price
\$ 3.5-10.74 . . . . .	1,334,702	5.72	\$ 7.75	988,140	\$ 6.71
11.22-17.86 . . . . .	1,768,645	8.14	14.47	359,658	13.78
18.06-35.76 . . . . .	1,471,104	7.10	27.99	788,591	27.98
35.91-93.81 . . . . .	1,294,801	6.65	65.22	966,269	66.37
	<u>5,869,252</u>	7.00	27.53	<u>3,102,658</u>	31.52

As of June 30, 2004, 30,000 warrants previously granted to placement agents were outstanding and exercisable at a weighted average price of \$40.00 per share.

**(5) Income Taxes**

The Company recorded \$0, \$417,000, and \$500,000 of foreign income tax expense in 2004, 2003, and 2002, respectively. The difference between the expected tax benefit for all periods presented and the actual tax expense is primarily attributable to the effect of net operating losses being offset by an increase in the Company's valuation allowance, plus the effect of foreign income taxes in 2003 and 2002.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities at June 30, 2004 and 2003 are presented below (in thousands):

	2004	2003
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 84,125	67,928
Unearned revenue . . . . .	281	1,104
Research and development credits . . . . .	7,763	6,455
Accrued liabilities and other . . . . .	1,729	1,589
Total gross deferred tax assets . . . . .	93,898	77,076
Less valuation allowance . . . . .	(93,288)	(76,813)
Net deferred tax assets . . . . .	610	263
Deferred tax liability:		
Equipment, principally due to differences in depreciation . . . . .	610	263
Total gross deferred tax liability . . . . .	610	263
Net deferred tax liability . . . . .	<u>\$ —</u>	<u>—</u>



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Notes to Consolidated Financial Statements (Continued)

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The net change in the total valuation allowance for the years ended June 30, 2004 and 2003 was an increase of \$16.5 million and \$13.1 million, respectively. Approximately \$36.4 million of deferred tax assets at June 30, 2004, if recognizable in future years, will be recognized as additional paid-in capital, and the remainder will be allocated as an income tax benefit to be reported in the consolidated statement of operations.

At June 30, 2004, the Company had total tax net operating losses of approximately \$225.5 million and total research and development credit carryforwards of approximately \$7.8 million, which can be carried forward to reduce federal income taxes. If not utilized, the tax loss and research and development credit carryforwards expire beginning in 2007 through 2024.

Under the rules of the Tax Reform Act of 1986, the Company has undergone changes of ownership, and consequently, the availability of the Company's net operating loss and research and experimentation credit carryforwards in any one year are limited. The maximum amount of carryforwards available in a given year is limited to the product of the Company's value on the date of ownership change and the federal long-term tax-exempt rate, plus any limited carryforward not utilized in prior years. Management does not believe that these rules will result in any losses or credits expiring unutilized.

**(6) Employee Deferred Savings Plan and Stock Purchase Plan**

The Company has a deferred savings plan which qualifies under Section 401(k) of the Internal Revenue Code. Substantially all of the Company's employees are covered by the plan. The Company makes matching contributions of 50% of each employee's contribution with the employer's contribution not to exceed 4% of the employee's compensation. The Company's contributions to the plan were \$970,000, \$858,000, and \$704,000 for the years ended June 30, 2004, 2003, and 2002, respectively.

The Company has an Employee Stock Purchase Plan (the Plan) which was adopted and approved by the board of directors and stockholders in December 1994, under which a maximum of 400,000 shares of common stock may be purchased by eligible employees. At June 30, 2004, 309,266 shares of common stock had been purchased under the Plan. Because the discount allowed to employees under the Plan approximates the Company's cost to issue equity instruments, the Plan is not deemed to be compensatory and, therefore, is excluded from the pro forma loss shown in note 1.

**(7) Collaborative Research Agreements**

In March 2002, the Company formed a drug discovery collaboration to identify novel drug targets for the diagnosis and treatment of depression. The agreement provided the collaborator with license rights and specified an upfront payment of \$4.4 million to the Company, plus guaranteed research funding, potential milestones and royalties. Revenue related to the license agreement is recognized ratably over the service period and revenue related to this research collaboration is recognized as the research is performed on a cost-to-cost basis. Revenue from the achievement of milestones is recognized upon achieving the milestone. Under this agreement the Company recognized research revenue of \$4.4 million, \$6.3 million, and \$2.0 million for the fiscal years ended June 30, 2004, 2003, and 2002, respectively.

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Notes to Consolidated Financial Statements (Continued)

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Also in March 2002, the Company formed a research collaboration whereby the Company applied its high-speed genomic sequencing capability and bioinformatics expertise to deliver molecular genetic information to the collaborator. The Company received \$24.0 million from this collaboration, which was completed in October 2003. Revenue related to this research collaboration was recognized on a straight-line basis. Under this contract the Company recognized research revenue of \$5.1 million, \$15.7 million, and \$3.2 million for the fiscal years ended June 30, 2004, 2003, and 2002, respectively.

In May 2000, the Company entered into a license agreement and research collaboration to utilize the Company's protein interaction technology (ProNet®). Under the agreement, the licensee received a license to utilize ProNet® and receive support and related upgrades from the Company on a when-and-if-available basis over the support period. The Company received \$22.5 million from this collaboration, which was completed in April 2003. Revenue related to the license agreement was recognized ratably over the service period and revenue related to the research collaboration was recognized as the costs of the contract were incurred on a cost-to-cost basis. Under this agreement the Company recognized research revenue of \$0, \$5.4 million, and \$8.0 million for the fiscal years ended June 30, 2004, 2003, and 2002, respectively.

In August 1999, and as expanded in December 2000, the Company entered into a two-year collaboration to perform research related to crop genomics. The Company received \$33.5 million from this collaboration, which was completed in December 2001. Revenue related to this research collaboration was recognized as the research was performed on a cost-to-cost basis. Under this agreement the Company recognized research revenue of \$0, \$0, and \$7.5 million for the fiscal years ended June 30, 2004, 2003, and 2002, respectively.

In September 1995, and as expanded in 1997 and 1998, the Company entered into a collaborative research and license agreement to perform research for a pharmaceutical company. Under the agreement, as expanded, the Company received \$38.7 million through December 2001 when the project was completed. Revenue related to this project was recognized as the research was performed on a cost-to-cost basis. Under this agreement the Company recognized research revenue of \$0, \$0, and \$2.3 million for the fiscal years ended June 30, 2004, 2003, and 2002, respectively.

Under some agreements the Company may license to the collaborator certain rights to therapeutic applications. The Company is entitled to receive royalties from sales of therapeutic products made by its collaborators. Because the Company has granted therapeutic rights to some of its collaborative licensees, the success of the programs is partially dependent upon the efforts of the licensees.

Each of the above agreements may be terminated early. If any of the licensees terminate the above agreements, such termination may have a material adverse effect on the Company's operations.

**(8) Segment and Related Information**

The Company's business units have been aggregated into three reportable segments: (i) research, (ii) predictive medicine, and (iii) drug development. The research segment is focused on the discovery of genes related to major common diseases. The predictive medicine segment provides testing to determine predisposition to common diseases. The drug development segment is focused on the development of therapeutic products for the treatment and prevention of major diseases.

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The accounting policies of the segments are the same as those described in the summary of significant accounting policies (note 1). The Company evaluates segment performance based on loss from operations before interest income and expense and other income and expense.

	<u>Research</u>	<u>Predictive medicine</u>	<u>Drug development</u>	<u>Total</u>
Year ended June 30, 2004:				
Revenues .....	\$ 13,354	43,294	—	56,648
Depreciation and amortization .....	2,273	1,768	1,725	5,766
Segment operating gain (loss) .....	(16,581)	2,975	(29,029)	(42,635)
Year ended June 30, 2003:				
Revenues .....	29,638	34,683	—	64,321
Depreciation and amortization .....	2,287	1,912	1,076	5,275
Segment operating gain (loss) .....	(2,811)	(2,672)	(21,863)	(27,346)
Year ended June 30, 2002:				
Revenues .....	27,015	26,821	—	53,836
Depreciation and amortization .....	2,395	1,602	499	4,496
Segment operating gain (loss) .....	(1,766)	(4,416)	(12,478)	(18,660)
		<u>2004</u>	<u>2003</u>	<u>2002</u>
Total operating loss for reportable segments .....		\$(42,635)	(27,346)	(18,660)
Unallocated amounts:				
Interest income .....		2,025	2,900	5,385
Other .....		(10)	38	(214)
Income taxes .....		—	(417)	(500)
Net loss .....		<u>\$(40,620)</u>	<u>(24,825)</u>	<u>(13,989)</u>

All of the Company's revenues were derived from research and testing performed in the United States. Additionally, all of the Company's long-lived assets are located in the United States. All of the Company's research segment revenue was generated from five, six, and seven collaborators in fiscal 2004, 2003, and 2002, respectively. Further, revenue from zero, one, and two of the collaborators was in excess of 10% of the Company's consolidated revenues for fiscal years 2004, 2003, and 2002, respectively.

**(9) Investment in Prolexys Pharmaceuticals, Inc.**

In April 2001, the Company contributed technology to Prolexys Pharmaceuticals, Inc. (Prolexys), formerly known as Myriad Proteomics, Inc., in exchange for a 49% ownership interest and investors contributed a combined \$82 million in cash in exchange for the remaining 51% ownership in Prolexys.

The Company accounts for its investment in Prolexys using the equity method. Because the Company's initial investment in Prolexys consisted of technology with a carrying value of \$0 on the Company's consolidated financial statements, and given the uncertainty of the realizability of the

**MYRIAD GENETICS, INC.  
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June 30, 2004 and 2003

difference between the \$82 million carrying amount and the Company's proportionate share of the net assets of Prolexys, the Company's initial investment in Prolexys was recorded as \$0. The Company allocated \$41 million of this difference to technology which is being reduced as the related technology amortization, including in-process research and development charges, are recorded at Prolexys. At June 30, 2004, the remaining technology basis difference is estimated to be \$12.5 million. The remaining \$41 million of unallocated basis difference is being accreted to income, offset by the Company's share of Prolexys' losses, over the period of expected benefit of 10 years.

As part of the formation of Prolexys, the Company entered into administrative and scientific outsourcing agreements with Prolexys. The original terms of these agreements expired on December 31, 2001, but were extended until June 30, 2002 and again to June 30, 2003 at the option of Prolexys. This agreement was terminated effective January 26, 2004.

Charges to Prolexys for services incurred related to the administrative and scientific outsourcing agreements are based on actual time and expenses incurred by the Company on behalf of Prolexys. During the years ended June 30, 2004, 2003, and 2002, the Company provided \$1.6 million, \$2.0 million, and \$6.3 million, respectively, of administrative and scientific services to Prolexys. As of June 30, 2004, the Company has received all payments from Prolexys for these outsourcing services.

Summarized balance sheet information as of June 30, 2004 and 2003 for Prolexys is as follows (in thousands):

	2004	2003
	(Unaudited)	
Current assets	\$24,230	37,785
Noncurrent assets	49,375	58,897
Current liabilities	3,191	2,821
Noncurrent liabilities	16,349	19,169
Stockholders' equity	54,065	74,692

Summarized statement of operations information for Prolexys for the years ended June 30, 2004, 2003, and 2002 is as follows (in thousands):

	2004	2003	2002
	(Unaudited)		
Total revenues	\$ 1,108	150	—
Other operating costs and expenses	23,828	23,155	28,478
Net loss	20,441	19,756	24,288

### **PART III**

#### **Item 10. DIRECTORS AND OFFICERS OF THE REGISTRANT**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Management”, “Section 16(a) Beneficial Ownership Reporting Compliance” and “Corporate Code of Conduct and Ethics” in our Proxy Statement for the 2004 Annual Meeting of Stockholders to be held on November 11, 2004.

#### **Item 11. EXECUTIVE COMPENSATION**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Executive Compensation,” “Management—Committees of the Board of Directors and Meetings—Compensation Committee Interlocks and Insider Participation,” and “Management—Compensation of Directors” in our Proxy Statement for the 2004 Annual Meeting of Stockholders to be held on November 11, 2004.

#### **Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation—Equity Compensation Plan Information” in our Proxy Statement for the 2004 Annual Meeting of Stockholders to be held on November 11, 2004.

#### **Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Certain Relationships and Related Transactions” in our Proxy Statement for the 2004 Annual Meeting of Stockholders to be held on November 11, 2004.

#### **Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The response to this item is incorporated by reference from the discussion responsive thereto in the proposal entitled “Independent Public Accountants (Notice Item 4)” in our Proxy Statement for the 2004 Annual Meeting of the Stockholders to be held on November 11, 2004.

## PART IV

### Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

#### Item 15(a).

The following documents are filed as part of this Annual Report on Form 10-K.

#### Item 15(a)(1) and (2).

See "Index to Consolidated Financial Statements and Financial Statement Schedules" at Item 8 to this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

#### Item 15(a)(3). Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description
(3.1 (a))i	—Restated Certificate of Incorporation of the Registrant (Filed as Exhibit 3.1 (a))
(3.1 (b))i	—Certificate of Amendment of Restated Certificate of Incorporation (Filed as Exhibit 3.1 (b))
(3.1 (c))i	—Certificate of Designations of Series A Junior Participating Preferred Stock (Filed as Exhibit 3.1 (c))
(3.2)p	—Restated By-Laws of the Registrant (Filed as Exhibit 3.2)
(4.1)	—See Exhibits 3.1(a), 3.1(b), 3.1(c) and 3.2
(4.2)h	—Form of Common Stock Certificate (Filed as Exhibit 4.2)
(4.3)n	—Rights Agreement dated as of July 17, 2001, between the Registrant and Mellon Investor Services, LLC (filed as Exhibit 4.1)
(4.4)h	—Agreement of Substitution and Amendment of Common Shares Rights Agreement by and between the Registrant and American Stock Transfer and Trust Company dated August 16, 2002 (Filed as Exhibit 4.4)
(10.1)\$h	—2002 Amended and Restated Employee, Director and Consultant Stock Option Plan (Filed as Exhibit 10.1)
(10.2)\$j	—2003 Employee, Director and Consultant Stock Option Plan (Filed as Exhibit 10.1)
(10.3)*\$	—Employee Stock Purchase Plan (Filed as Exhibit 10.2)
(10.4)*\$	—Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Peter D. Meldrum, dated May 15, 1993 (Filed as Exhibit 10.3)
(10.5)*\$	—Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Mark H. Skolnick, Ph.D., dated January 1, 1994 (Filed as Exhibit 10.4)
(10.6)*\$	—Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Jay M. Moyes, dated July 12, 1993 (Filed as Exhibit 10.5)
(10.7)\$	—Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Gregory C. Critchfield, M.D., dated September 14, 1998

Exhibit Number	Description
(10.8)\$	—Employment Agreement between Myriad Genetics, Inc., Myriad Pharmaceuticals, Inc. and Adrian N. Hobden, Ph.D., dated September 30, 1998
(10.9)#	—Exclusive License Agreement between the Registrant and the University of Utah Research Foundation, dated October 8, 1991, as amended (Breast Cancer—BRCA1) (Filed as Exhibit 10.13)
(10.10)#	—Exclusive License Agreement between the Registrant and the University of Utah Research Foundation, dated June 21, 1994 (MTS1 or p16) (Filed as Exhibit 10.16)
(10.11)#	—Exclusive License Agreement between the Registrant and the University of Utah Research Foundation, dated November 23, 1994 (Breast Cancer—BRCA2) (Filed as Exhibit 10.17)
(10.12)#	—Exclusive License Agreement dated May 1, 1995 between the Registrant and the University of Utah Research Foundation (Cardiovascular Disorders and Coronary Heart Disease Database) (Filed as Exhibit 10.19)
(10.13)#	—Exclusive License Agreement dated July 31, 1995 between the Registrant and the University of Utah Research Foundation (Obesity Database) (Filed as Exhibit 10.21)
(10.14)#	—Collaborative Research and License Agreement between the Registrant and Bayer Corporation, dated September 11, 1995 (Filed as Exhibit 10.28)
(10.15)!	—Lease Agreement, dated October 12, 1995, between the Boyer Research Park Associates V, by its general partner, the Boyer Company and the Registrant (Filed as Exhibit 10.2)
(10.16)!	—Amendment to Lease Agreement, dated March 29, 1996 between the Boyer Research Park Associates V, by its general partner, the Boyer Company and the Registrant (Filed as Exhibit 10.3)
(10.17)q@	—Patent and Technology License Agreement dated December 2, 1996 among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center and the Registrant (Filed as Exhibit 10.1)
(10.18)%@	—Amendment and Supplement to Collaborative Research and License Agreement dated November 19, 1997 between Bayer Corporation and the Registrant (Filed as Exhibit 10.1)
(10.19)k	—Lease Agreement—Research Park Building Phase II, dated March 6, 1998, between the Research Park Associated VI, by its general partner, the Boyer Company, L.C. and the Registrant (Filed as Exhibit 10.44)
(10.20)&	—Memorandum of Lease between the Company and Boyer Foothill Associates, Ltd. dated August 24, 1998 (Filed as Exhibit 10.1)
(10.21)&	—Memorandum of Lease between the Company and Boyer Research Park Associates VI, L.C. dated August 24, 1998 (Filed as Exhibit 10.2)
(10.22)&	—Subordination Agreement and Estoppel, Attornment and Non-Disturbance Agreement (Lease to Deed of Trust) between the Company and Wells Fargo Bank, National Association dated June 24, 1998 (Filed as Exhibit 10.3)
(10.23)w@	—Letter Amendment to the Collaborative Research and License Agreement dated as of November 30, 1998 between Bayer Corporation and the Company (Filed as Exhibit 10.10)

Exhibit Number	Description
(10.24)e	—Lease Agreement, dated March 31, 2001 between the Registrant and Boyer Research Park Associates VI, by its general partner, The Boyer Company, L.C. (Filed as Exhibit 10.1)
(10.25)e	—Agreement, dated March 31, 2001, between the Registrant and Boyer Research Park Associates VI, by its general partner, The Boyer Company, L.C. (Filed as Exhibit 10.2)
(10.26)e@	—License Agreement, dated December 7, 2000, between the Registrant and Encore Pharmaceuticals, Inc. (Filed as Exhibit 10.3)
(21.1)	—List of Subsidiaries of the Registrant
(23.1)	—Consent of KPMG LLP
(31.1)	—Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002
(31.2)	—Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002
(32)	—Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

- \* Previously filed with the Commission as Exhibits to, and incorporated herein by reference from, the Company's Registration Statement filed on Form S-1, File No. 33-95970.
- # Previously filed with the Commission as Exhibits to, and incorporated herein by reference from, the Company's Registration Statement filed on Form S-1, File No. 33-95970, and for which Confidential Treatment has been granted by the Commission as to certain portions.
- @ Confidential Treatment has been granted by the Commission as to certain portions.
- p Previously filed and incorporated herein by reference from the Form 10-Q for the period ending September 30, 1995.
- \$ Management contract or compensatory plan or arrangement.
- ! Previously filed and incorporated herein by reference from the Form 10-Q for the period ending September 30, 1996.
- q Previously filed and incorporated herein by reference from the Form 10-Q for the period ending December 31, 1996.
- % Previously filed and incorporated herein by reference from the Form 10-Q for the period ending December 31, 1997.
- k Previously filed and incorporated herein by reference from the Form 10-K for the period ending June 30, 1998.
- & Previously filed and incorporated herein by reference from the Form 10-Q for the period ending September 30, 1998.
- w Previously filed and incorporated herein by reference from the Form 10-Q for the period ending December 31, 1998.
- e Previously filed and incorporated herein by reference from the Form 10-Q for the period ending March 31, 2001.
- h Previously filed and incorporated herein by reference from the Form 10-K for the period ending June 30, 2002.



- i Previously filed and incorporated herein by reference from the Form 10-K for the period ending June 30, 2001.
- j Previously filed and incorporated herein by reference from the Form 10-Q for the period ending December 31, 2003.
- n Previously filed and incorporated herein by reference from the Form 8-K filed on July 18, 2001.

Where a document is incorporated by reference from a previous filing, the Exhibit number of the document in that previous filing is indicated in parentheses after the description of such document.

**Item 15(b). Reports on Form 8-K**

On May 4, 2004, we furnished a Current Report on Form 8-K to disclose that we had publicly disseminated a press release announcing our financial results for the three and nine months ended March 31, 2004.

On June 4, 2004, we filed a Current Report on Form 8-K to disclose that we had publicly disseminated press releases announcing the commencement and completion of an underwritten public offering of 3,400,000 shares of our common stock pursuant to our outstanding shelf registration statement on Form S-3 resulting in the receipt of approximately \$50.1 million in net proceeds.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Salt Lake City, Utah on September 8, 2004.

### MYRIAD GENETICS, INC.

By: /s/ PETER D. MELDRUM

Peter D. Meldrum  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

Signatures	Title	Date
By: <u>/s/ PETER D. MELDRUM</u> Peter D. Meldrum	President and Chief Executive Officer and Director (principal executive officer)	September 8, 2004
By: <u>/s/ JAY M. MOYES</u> Jay M. Moyes	Vice President of Finance (principal financial and accounting officer)	September 8, 2004
By: <u>/s/ DALE A. STRINGFELLOW</u> Dale A. Stringfellow, Ph.D.	Chairman of the Board	September 8, 2004
By: <u>/s/ WALTER GILBERT</u> Walter Gilbert, Ph.D.	Vice Chairman of the Board	September 8, 2004
By: <u>/s/ MARK H. SKOLNICK</u> Mark H. Skolnick, Ph.D.	Chief Scientific Officer and Director	September 8, 2004
By: <u>/s/ ARTHUR H. HAYES, JR.</u> Arthur H. Hayes, Jr., M.D.	Director	September 8, 2004
By: <u>/s/ LINDA S. WILSON</u> Linda S. Wilson, Ph.D.	Director	September 8, 2004
By: <u>/s/ ROBERT S. ATTIYEH</u> Robert S. Attiyeh	Director	September 8, 2004
By: <u>/s/ JOHN T. HENDERSON</u> John T. Henderson, M.D.	Director	September 8, 2004
By: <u>/s/ DENNIS LANGER</u> Dennis Langer, M.D., J.D.	Director	September 8, 2004

## MYRIAD GENETICS, INC.

## Valuation and Qualifying Accounts

Years Ended June 30, 2004, 2003, and 2002

(In thousands)

	<u>Balance at Beginning of Period</u>	<u>Addition Charged to Cost and Expenses</u>	<u>Deductions(1)</u>	<u>Balance at End of Period</u>
<b>Allowance for doubtful accounts:</b>				
Year ended June 30, 2004 .....	\$895	\$2,020	\$(1,710)	\$1,205
Year ended June 30, 2003 .....	\$505	\$ 564	\$ (174)	\$ 895
Year ended June 30, 2002 .....	\$255	\$ 405	\$ (155)	\$ 505

(1) Represents amounts written off against the allowance.

See report of independent registered public accounting firm.